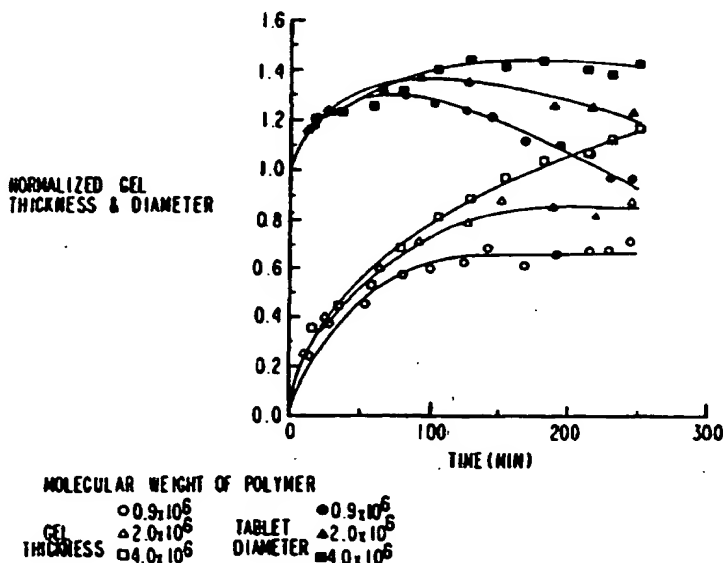




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(71) Applicant: TEMPLE UNIVERSITY OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION [US/US]; Broad & Oxford Streets, Philadelphia, PA 19122 (US).			
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(54) Title: CONTROLLED RELEASE TABLET



(57) Abstract

A controlled release tablet including a pharmaceutical agent and an excipient. The excipient includes at least about 60 % of a water swellable polymer and a lubricant. The water swellable polymer is chosen such that the swelling rate of the polymer is equal to the dissolution rate of the swollen polymer. The excipient may also include such other ingredients as diluents, fillers, binders, solubilizers, emulsifiers, and other pharmacologically inactive compounds. The polymer is chosen with the pharmaceutical agent in mind such that the tablet will be fully dissolved at the same time that the last of the pharmaceutical agent is released.

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 97/10737

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K9/20

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	C. J. KIM: "Drug release from compressed polyox-wsr tablets" JOURNAL OF PHARMACEUTICAL SCIENCES, vol. 84, no. 3, 1995, pages 303-306, XP002018917 see the whole document ---	1,3,4, 7-9,13, 17, 19-23, 27-33, 37,38
X	EP 0 661 045 A (YAMANOUCHI PHARMACEUTICAL CO. LTD) 5 July 1995 see claims 1,5,6 see page 3, line 1 - line 29 see page 3, line 49 - page 5, line 2 see page 8; table 3 see page 25; examples 12-14 --- -/--	1,3-17, 19-28, 30-38

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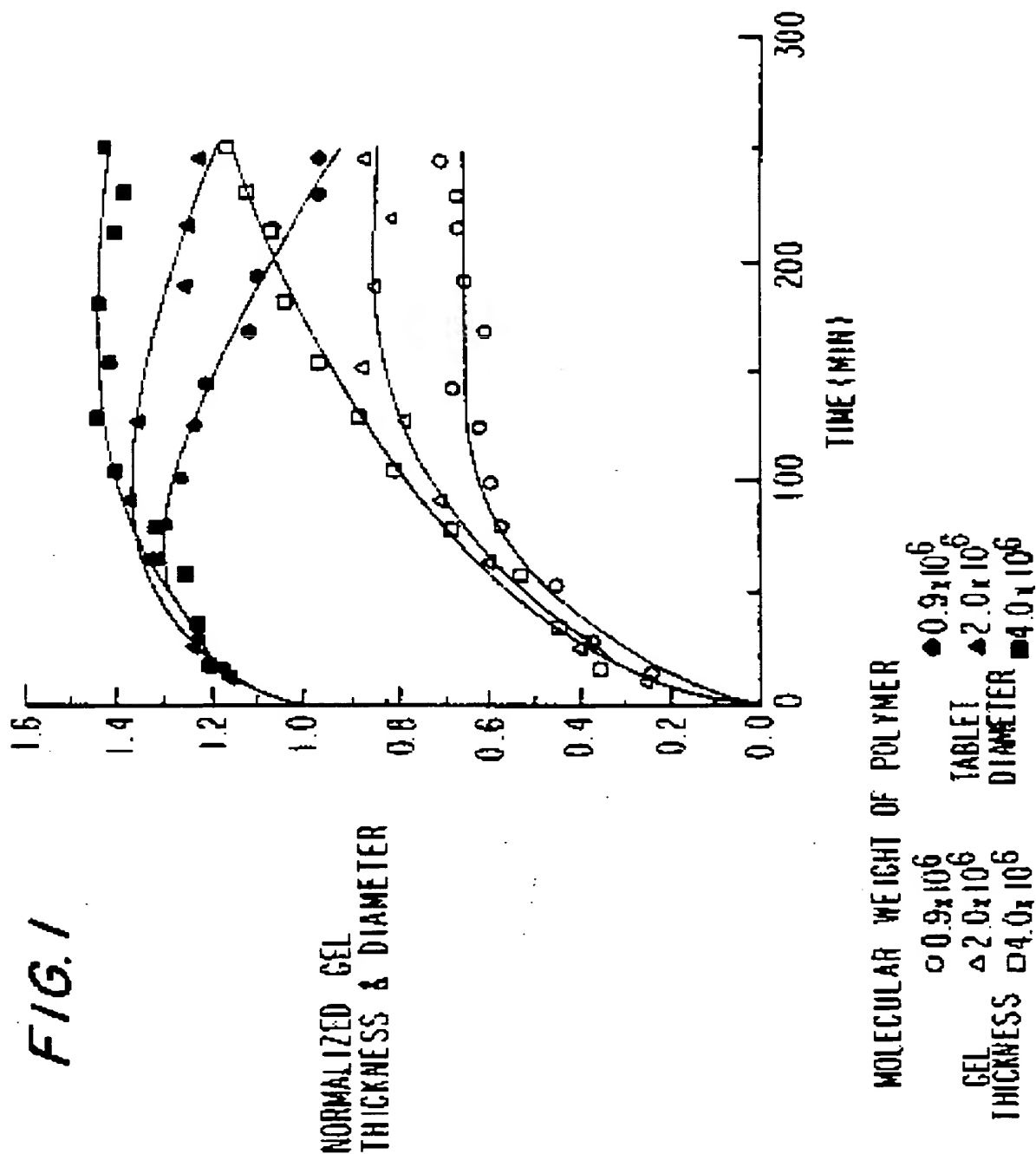
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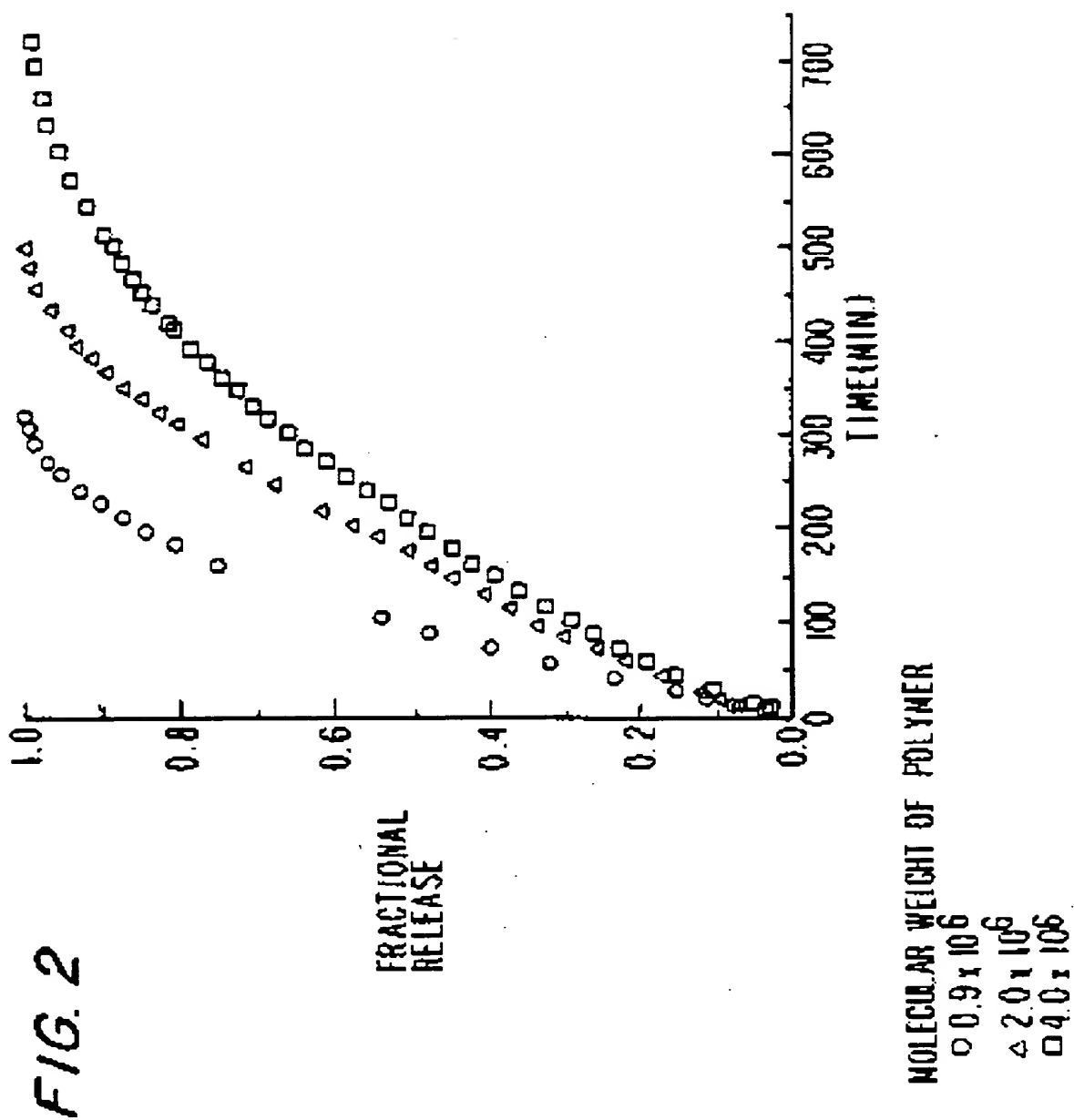
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 661045 A	05-07-95	AU 682827 B	23-10-97
		AU 4983893 A	12-04-94
		BG 99503 A	31-01-96
		FI 951226 A	16-03-95
		NO 951036 A	17-03-95
		SK 33895 A	08-11-95
		CA 2144077 A	31-03-94
		CN 1091004 A	24-08-94
		CZ 9500679 A	13-09-95
		HU 72324 A	29-04-96
		WO 9406414 A	31-03-94
		NZ 255579 A	26-03-96
		PL 308137 A	24-07-95
		ZA 9306798 A	14-04-94
EP 231826 A	12-08-87	US 4837032 A	06-06-89
		CA 1273876 A	11-09-90
		DE 3774889 A	16-01-92
		ES 2055689 T	01-09-94
		JP 63057523 A	12-03-88
WO 9626718 A	06-09-96	AU 5171196 A	18-09-96

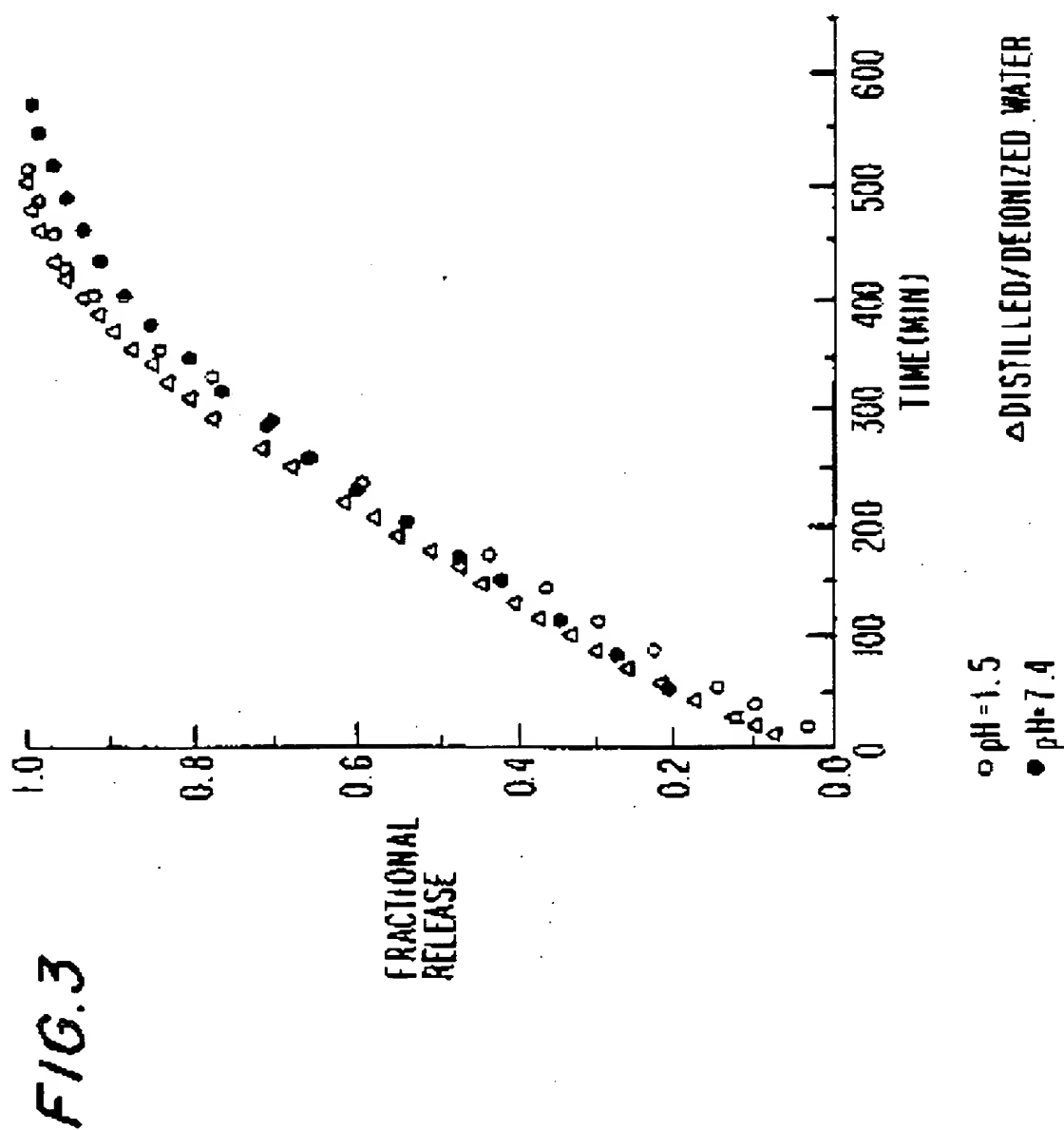
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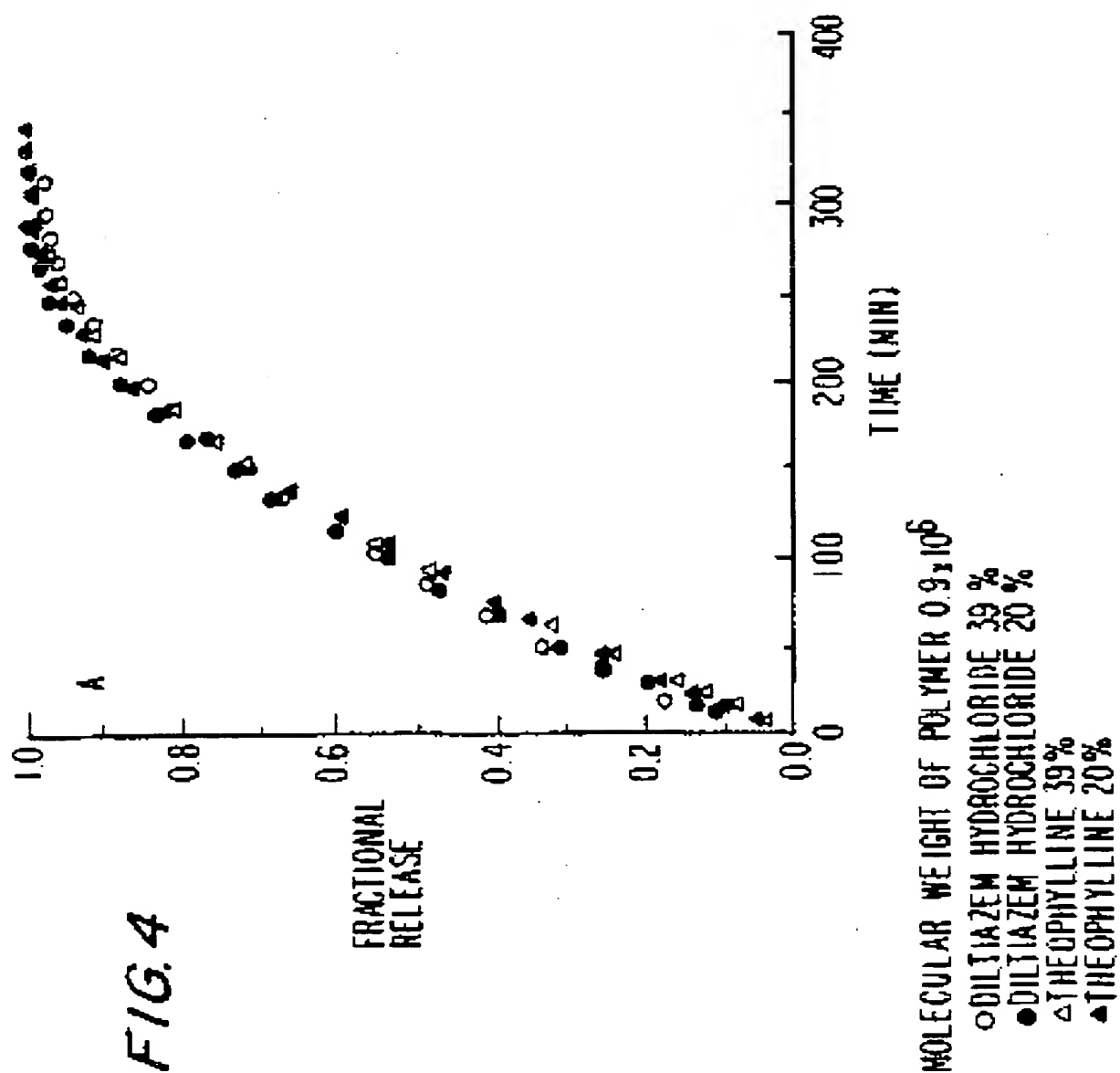


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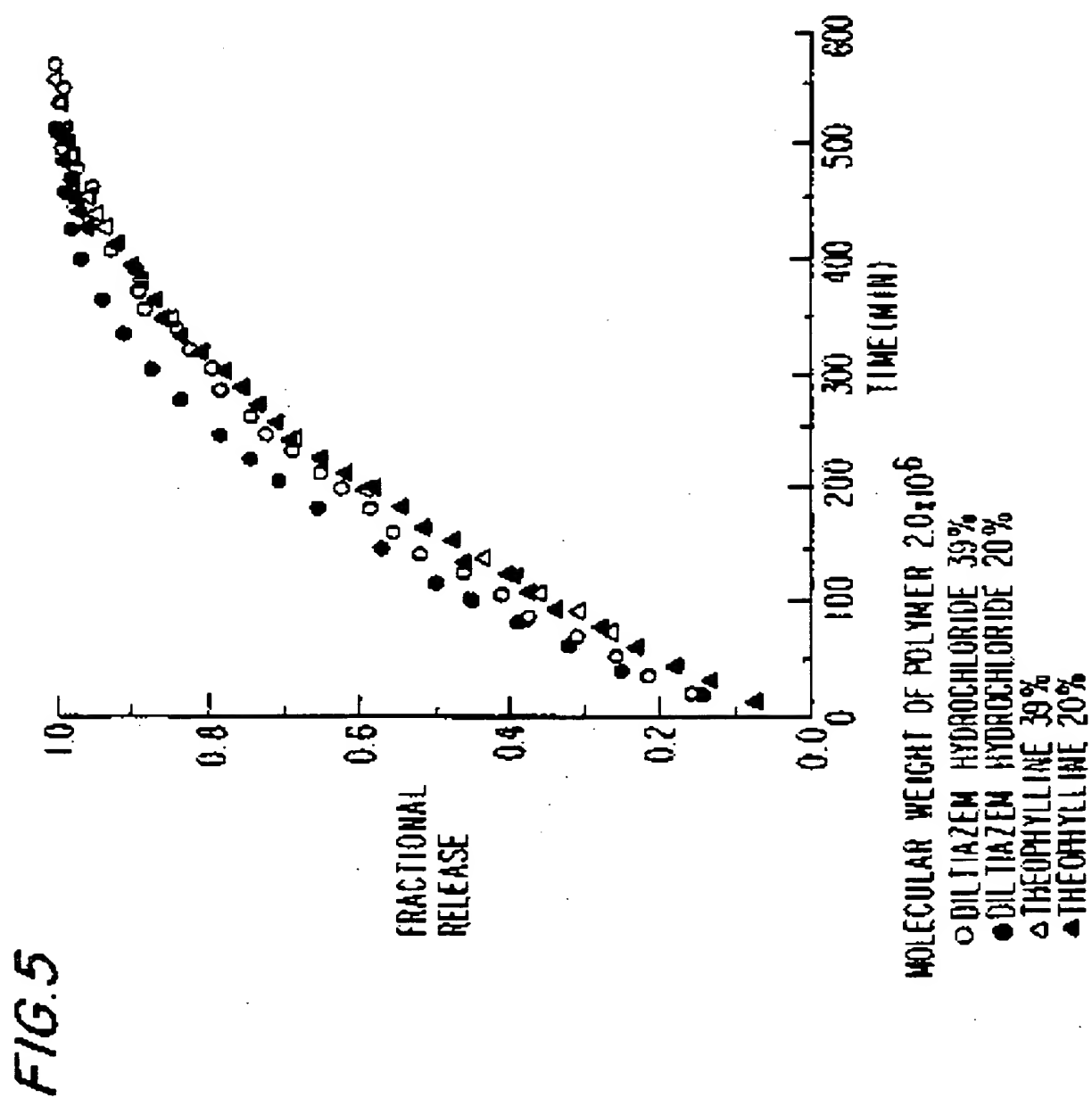
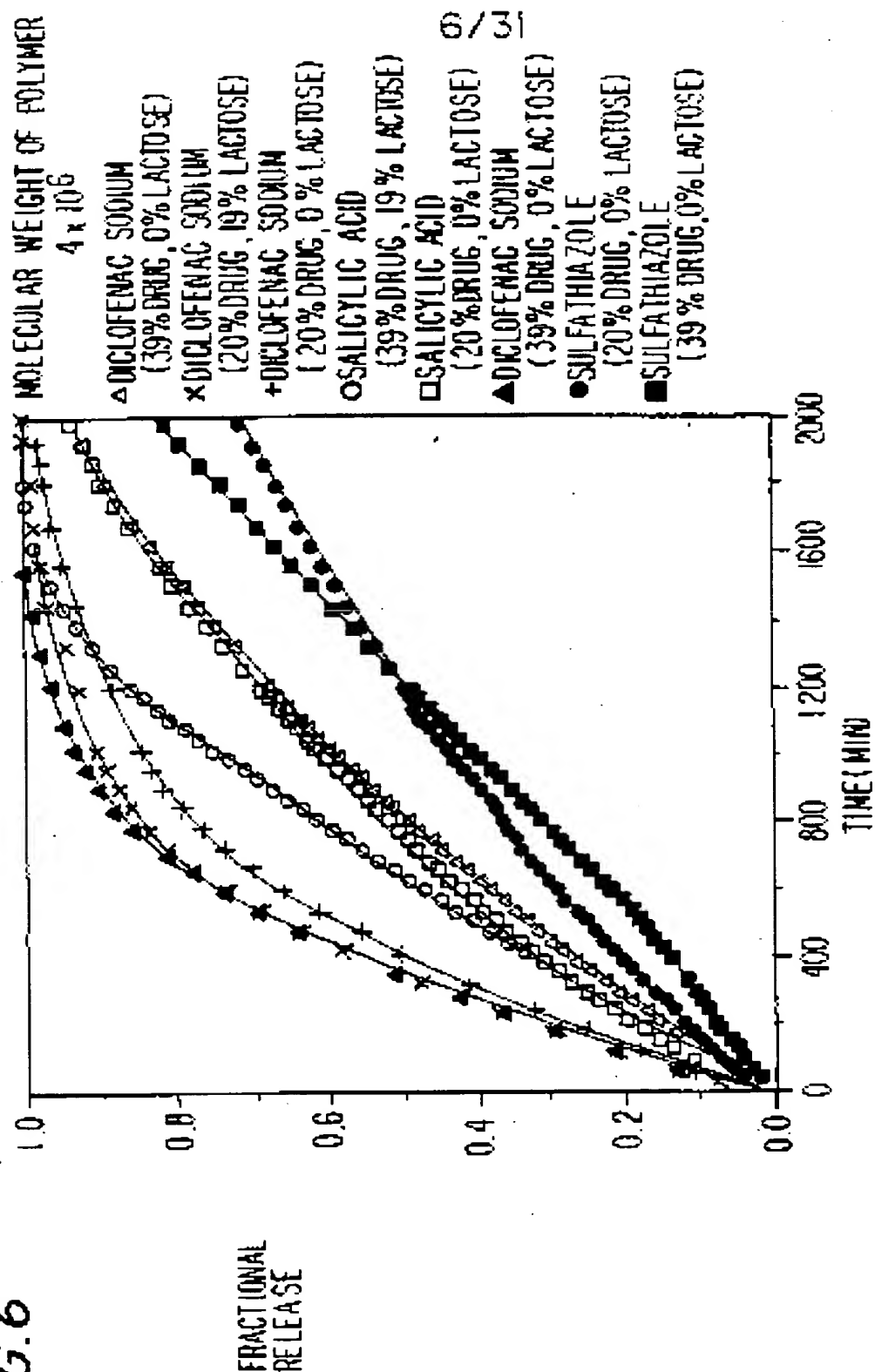
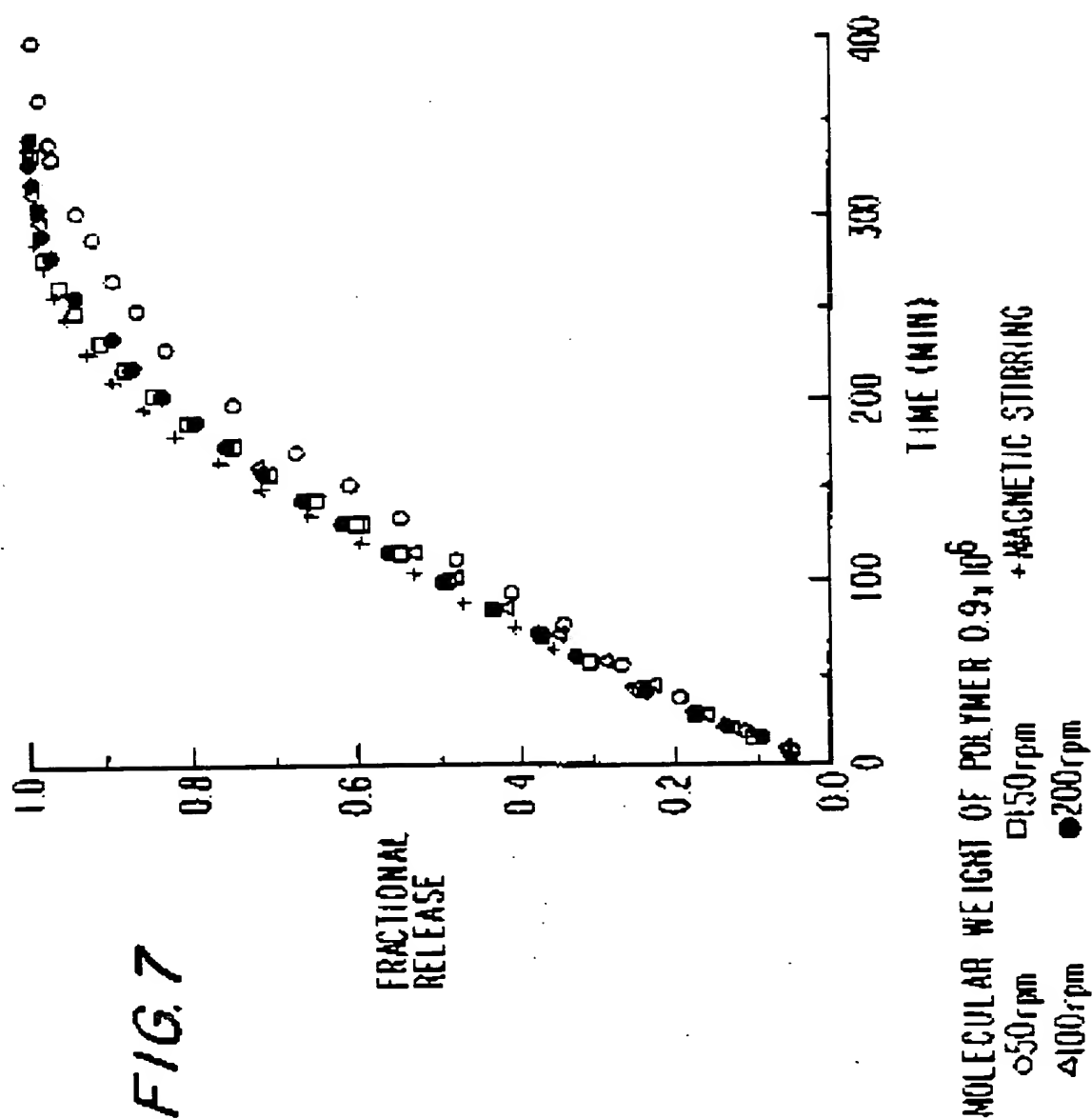


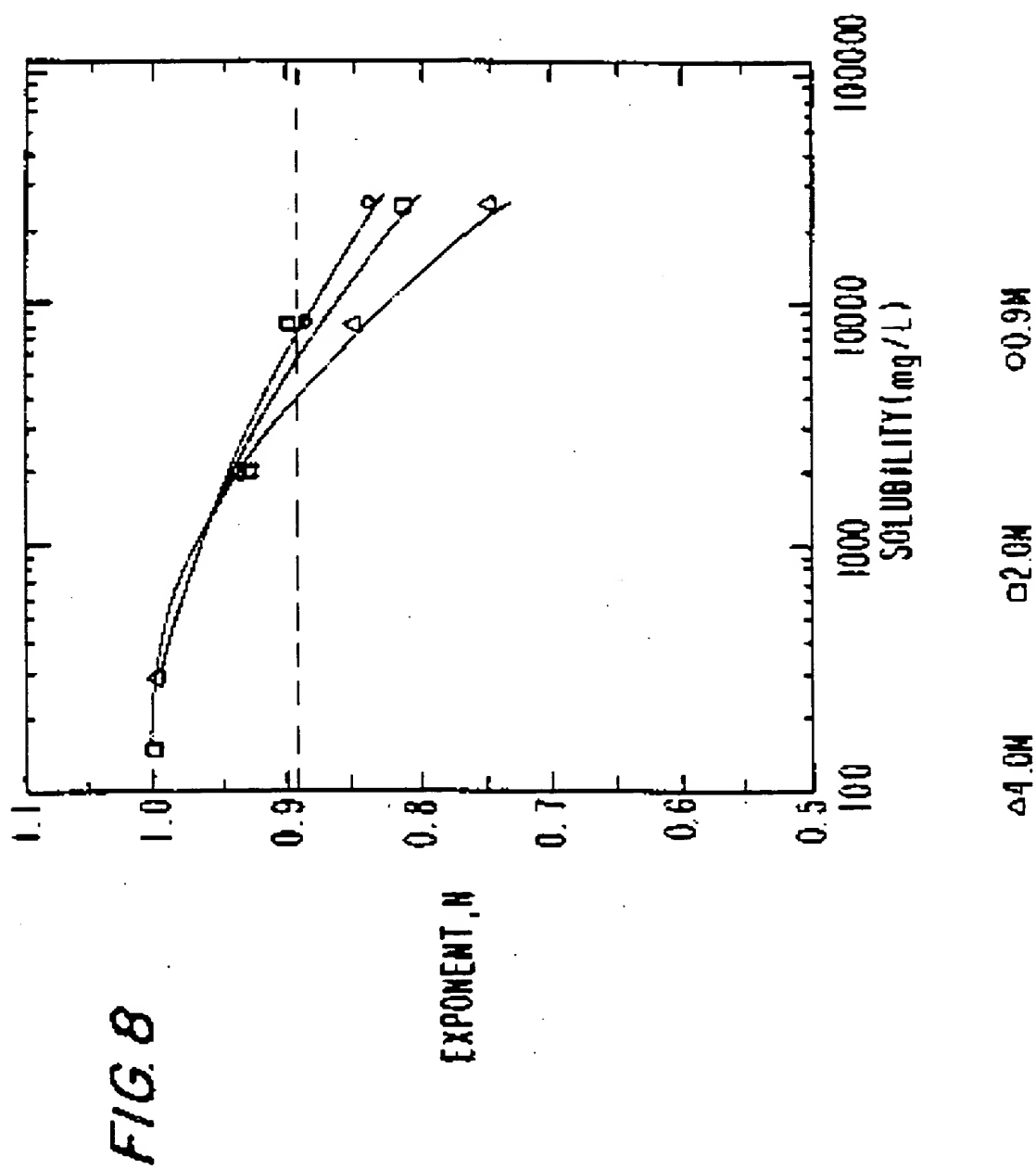
FIG. 6



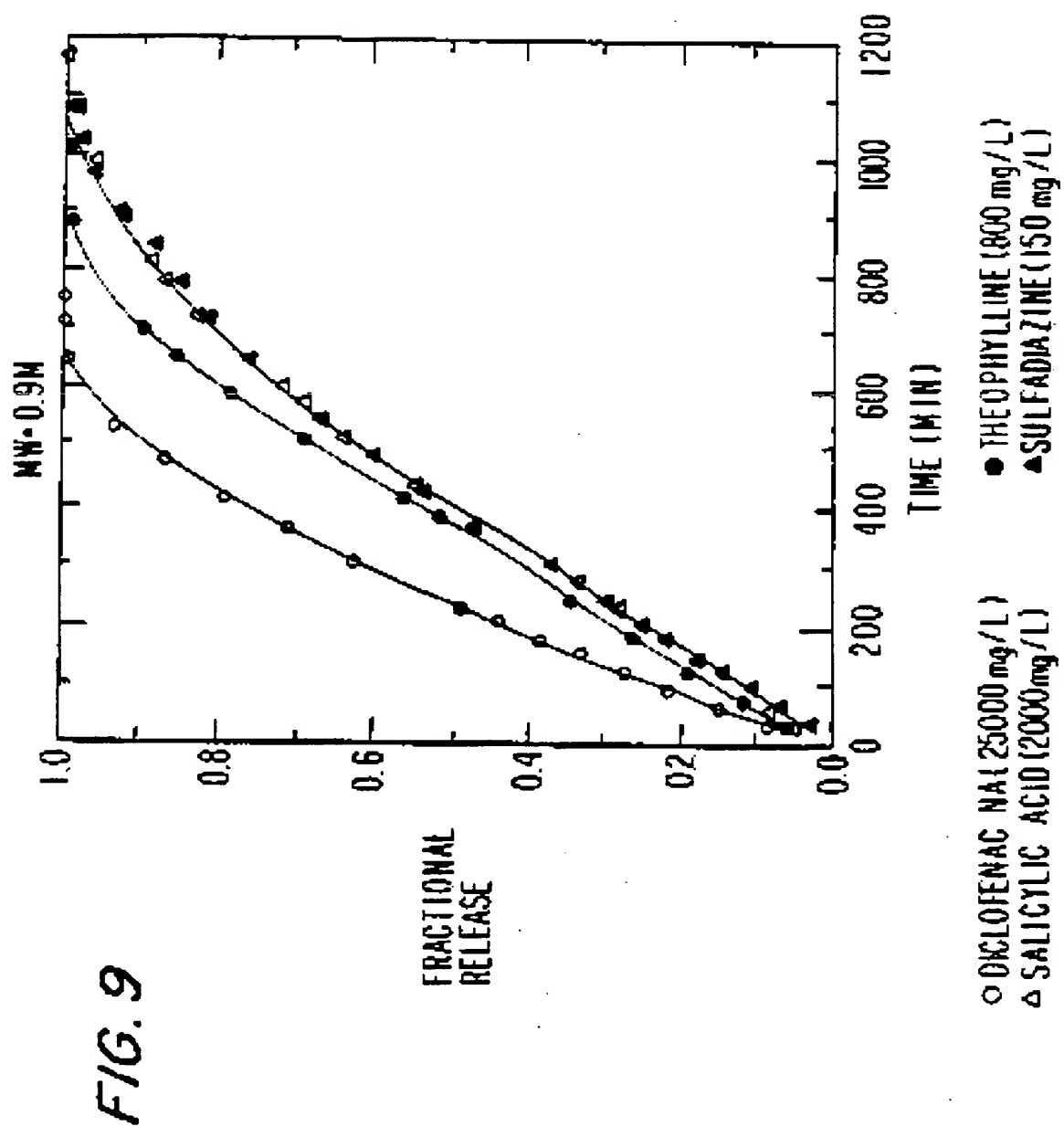
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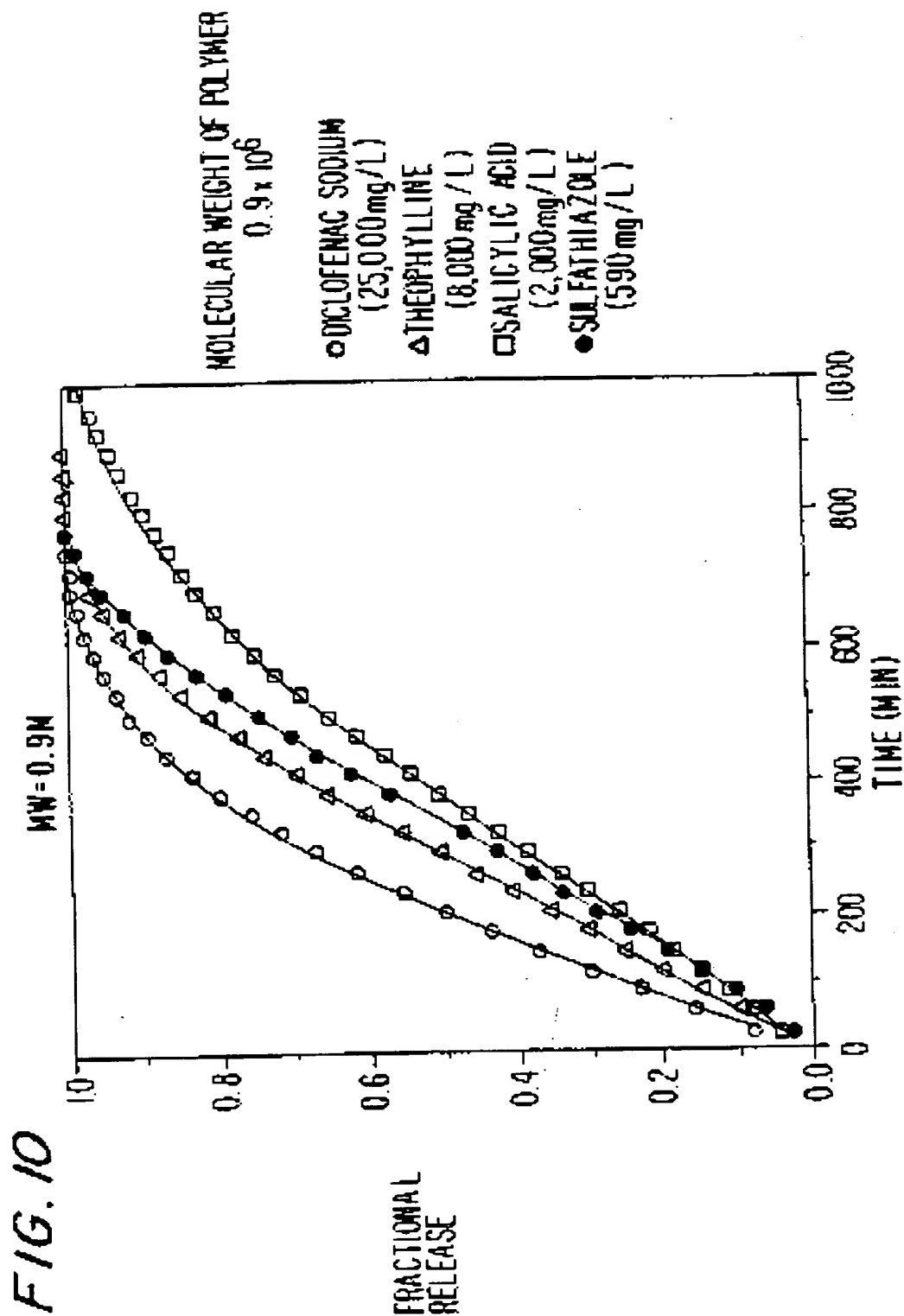
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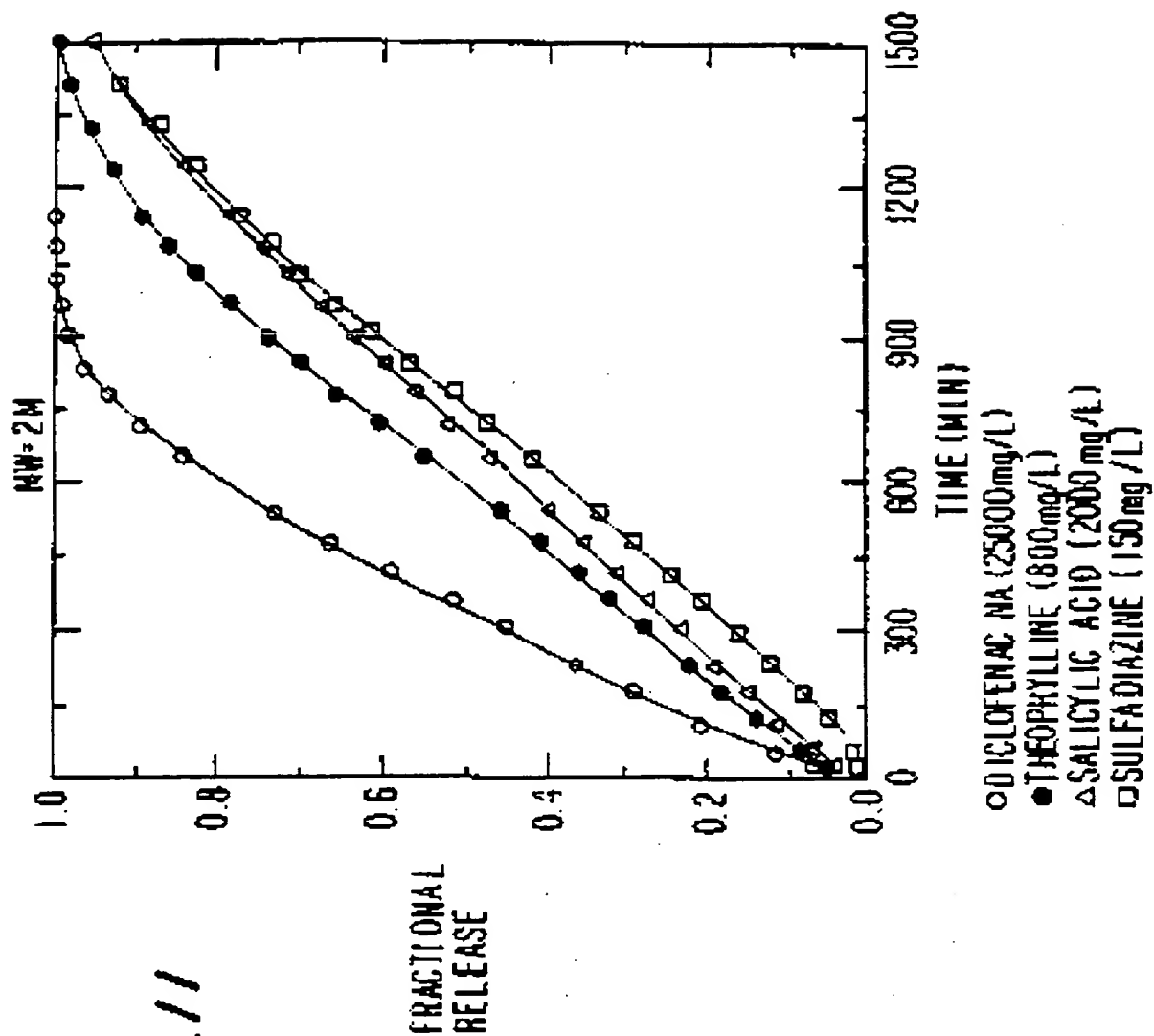
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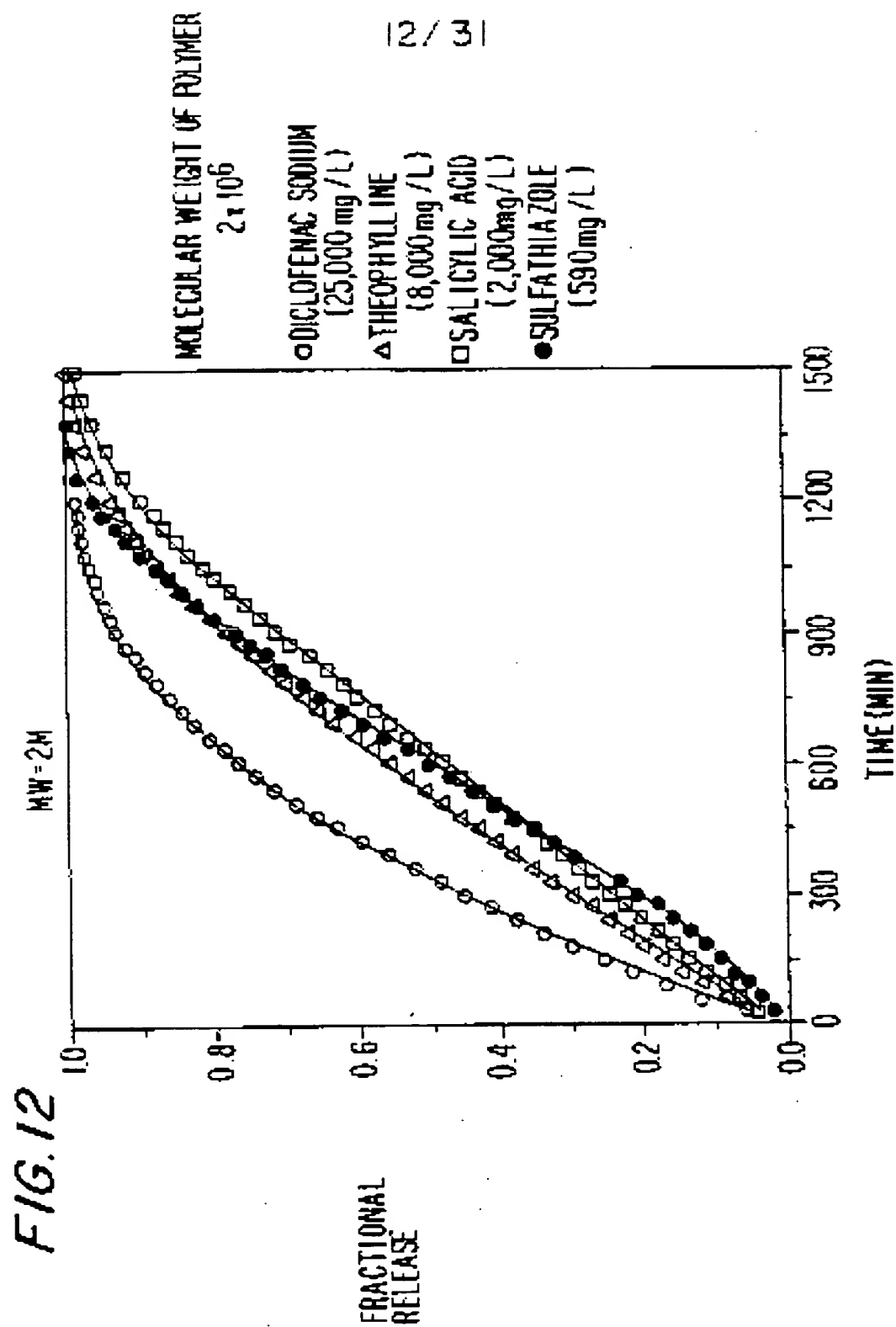


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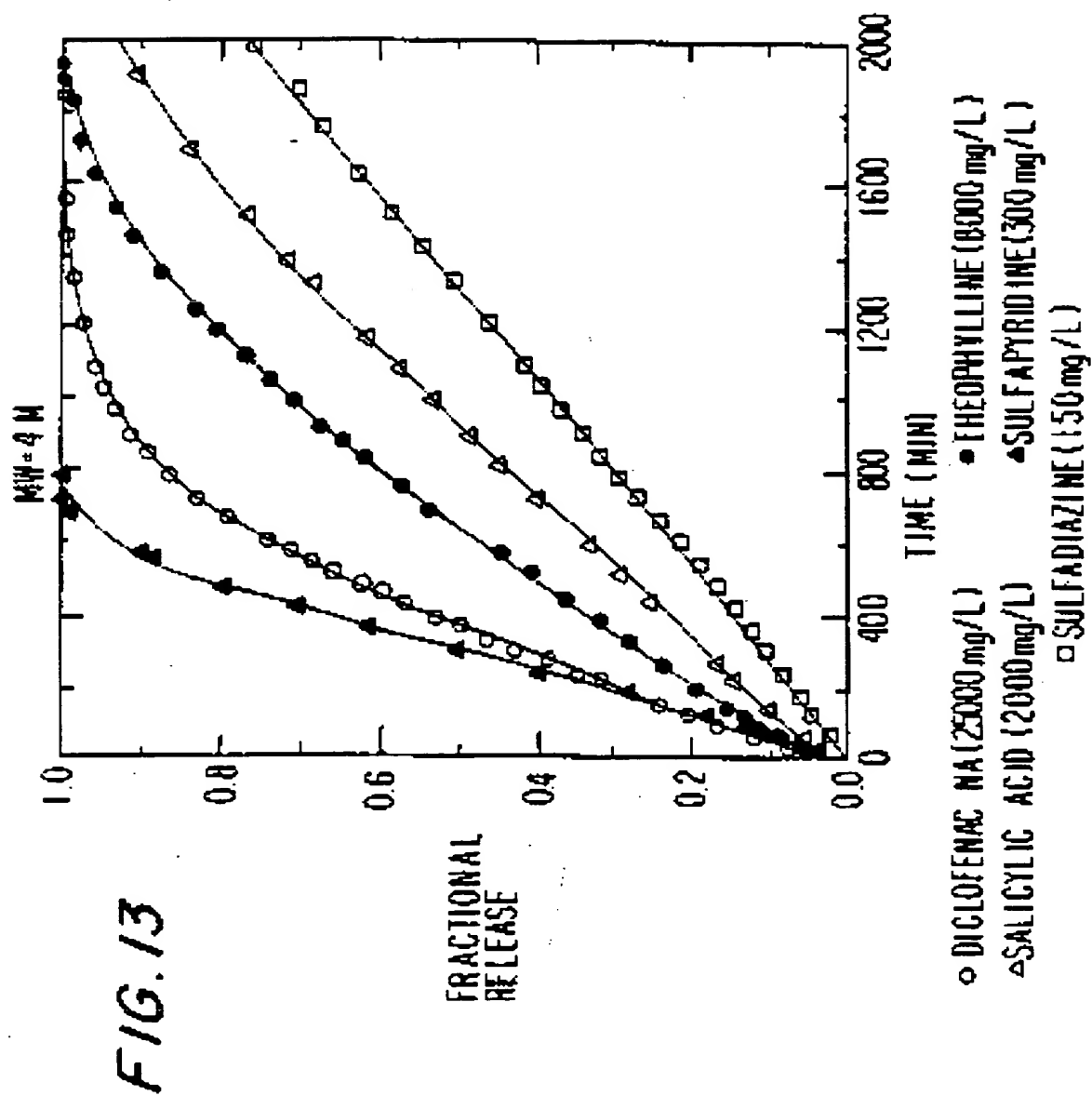


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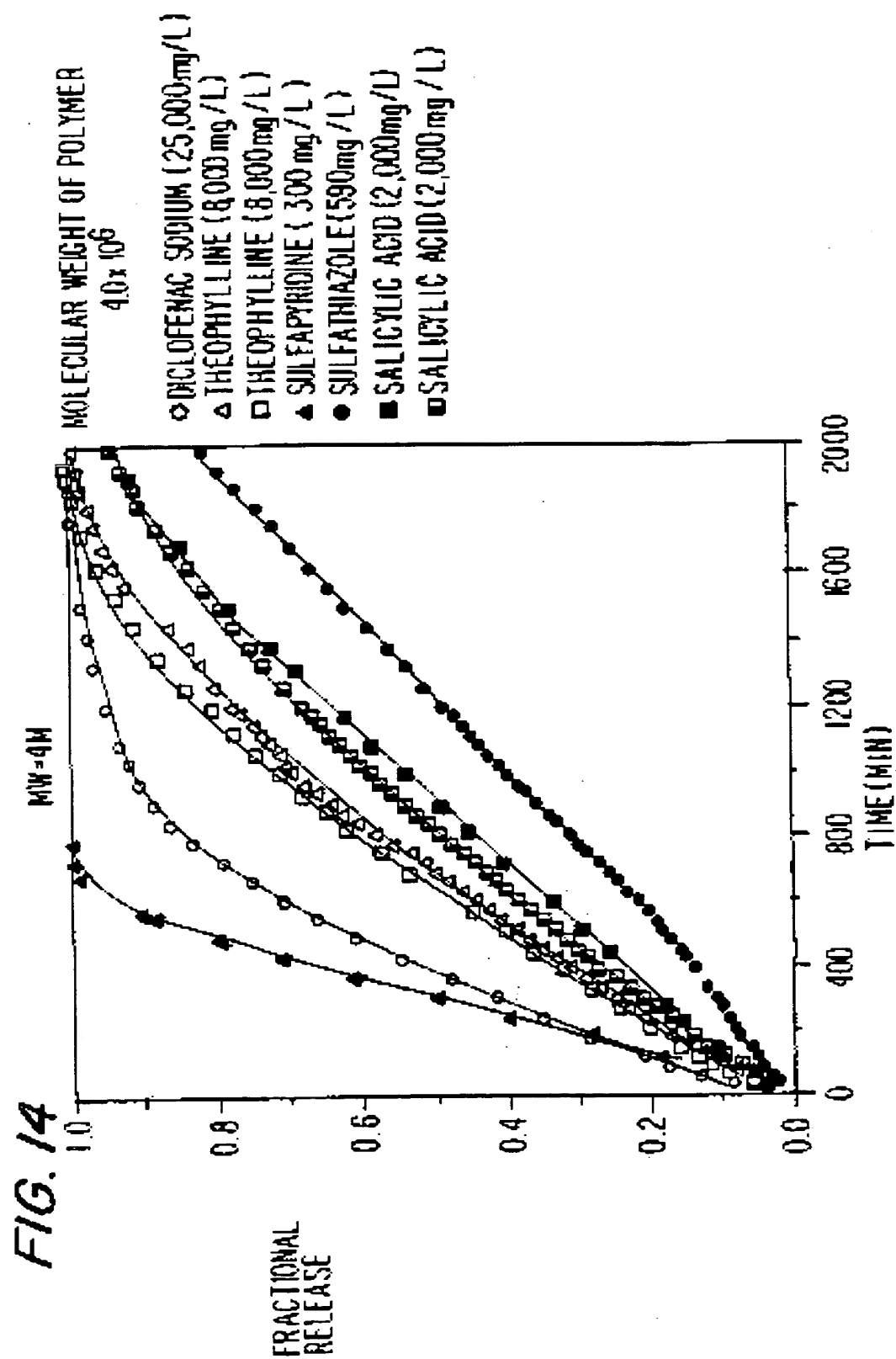




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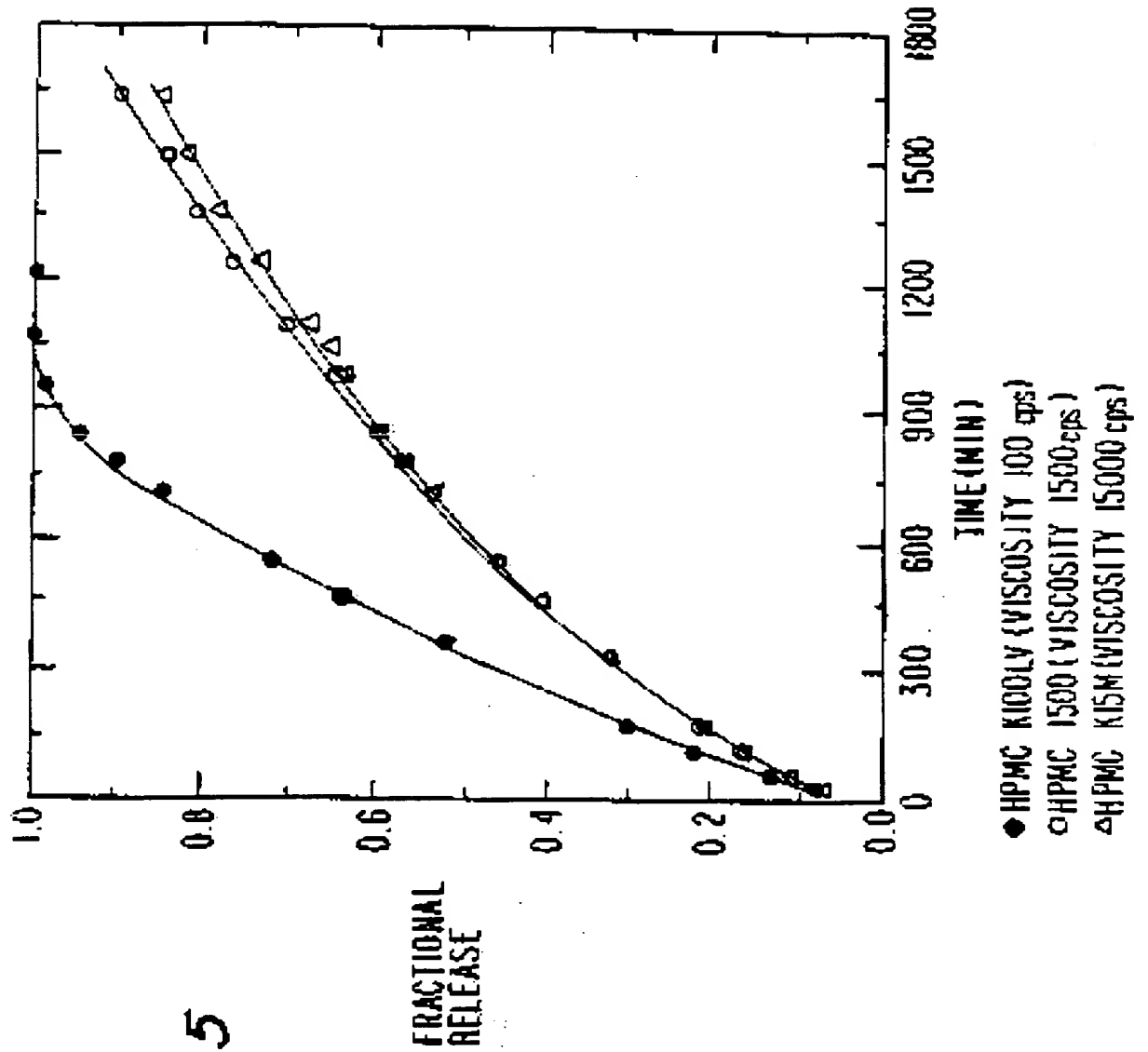
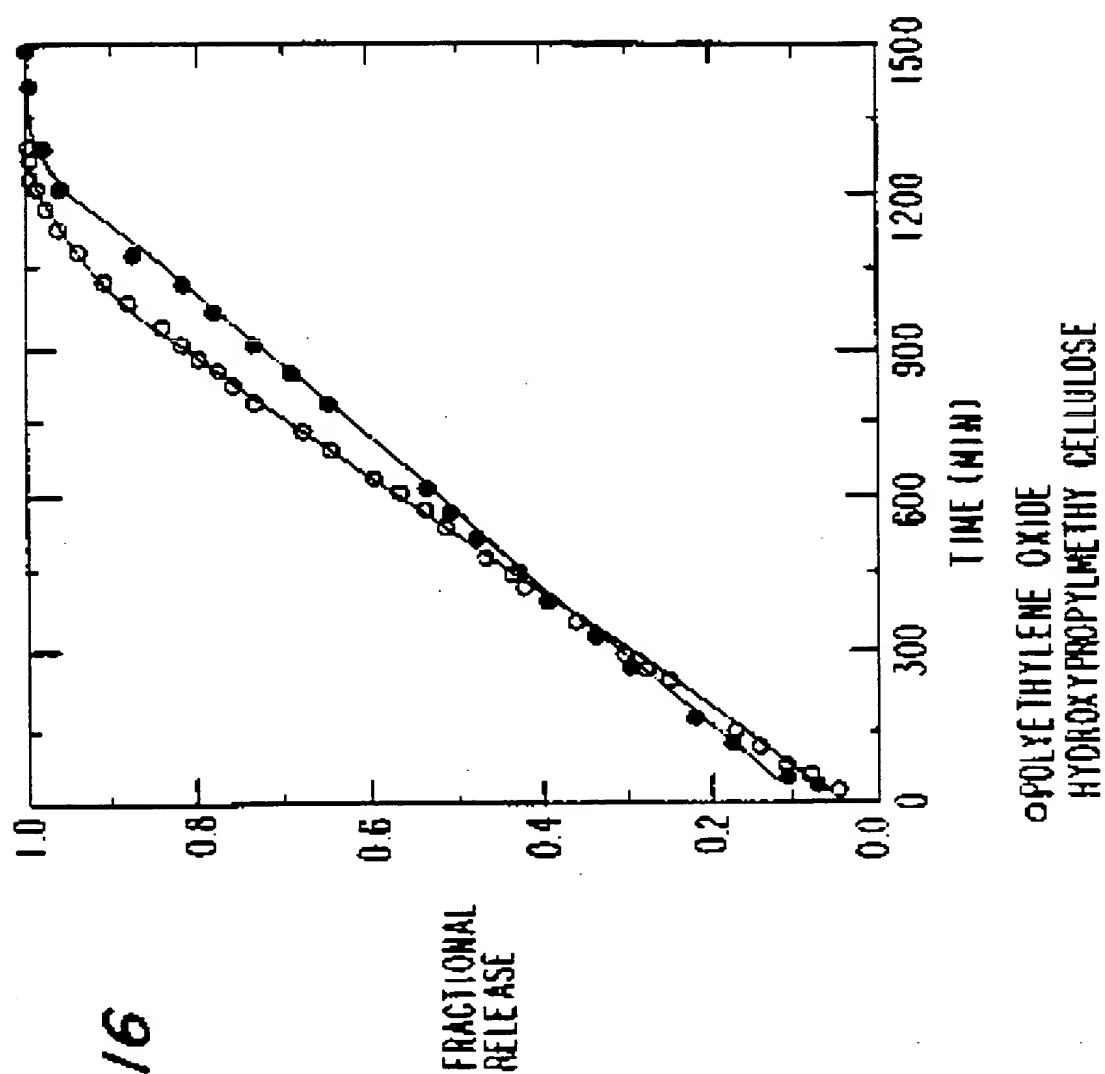


FIG. 15

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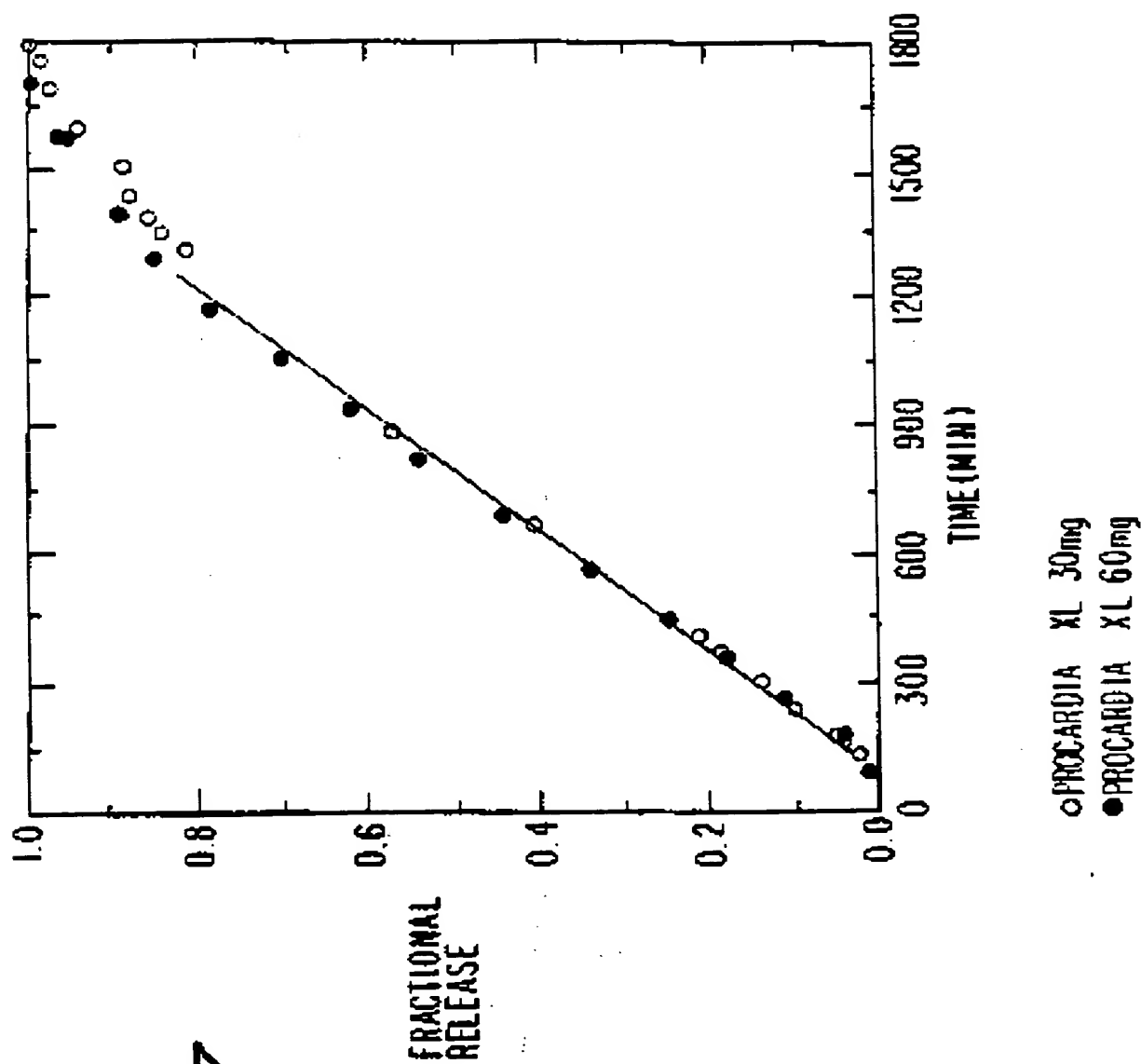
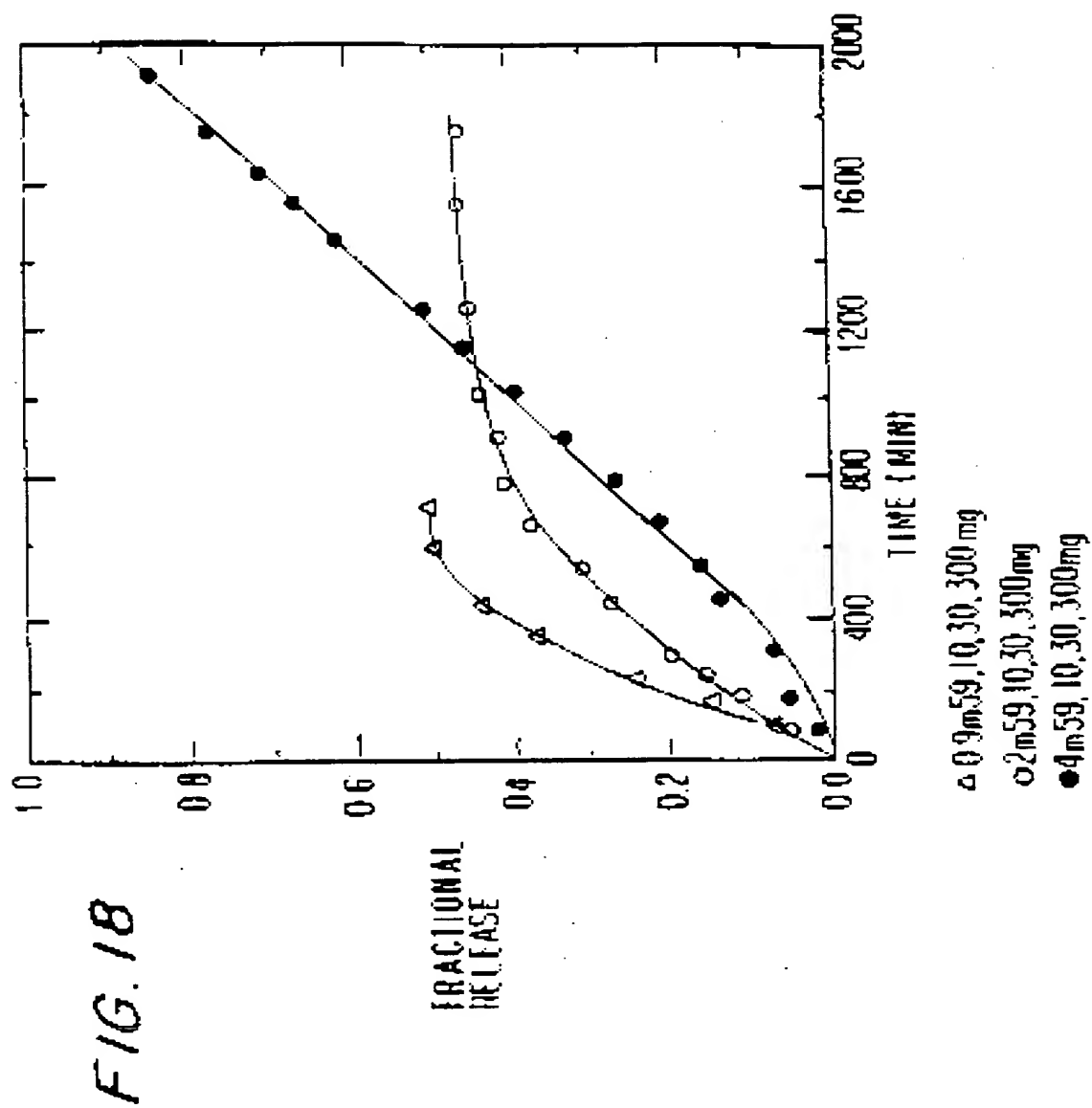
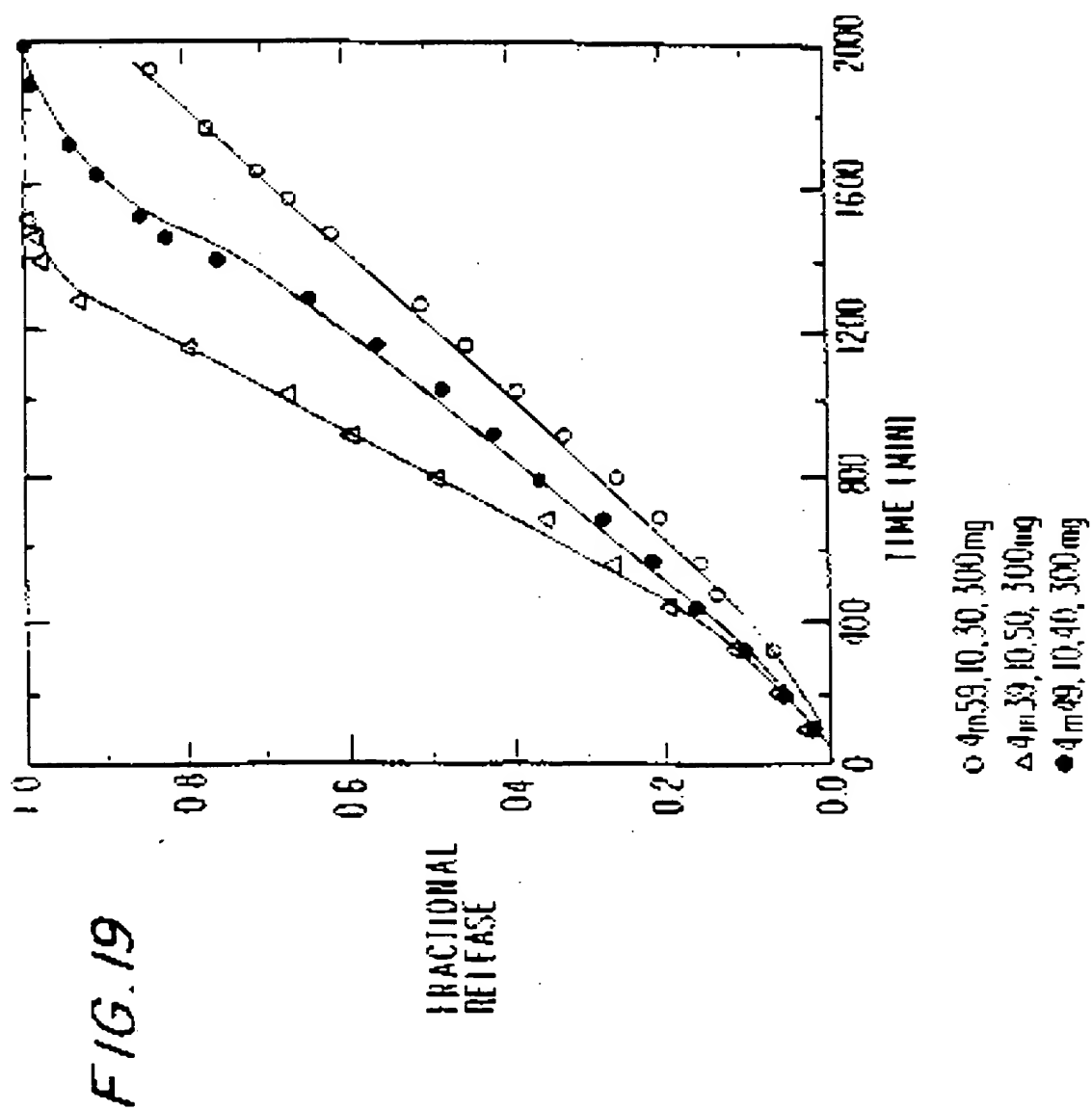


FIG. 17

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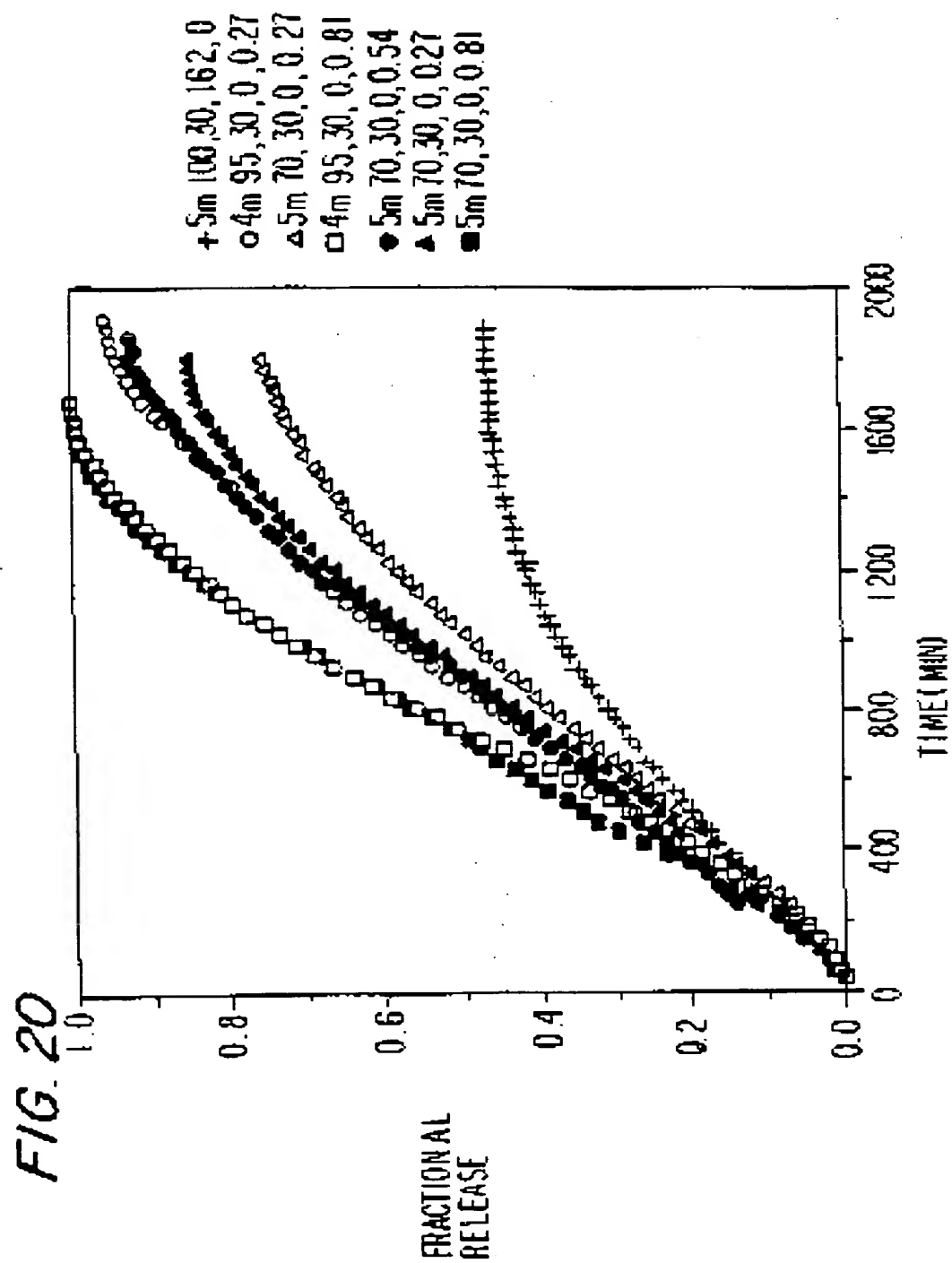


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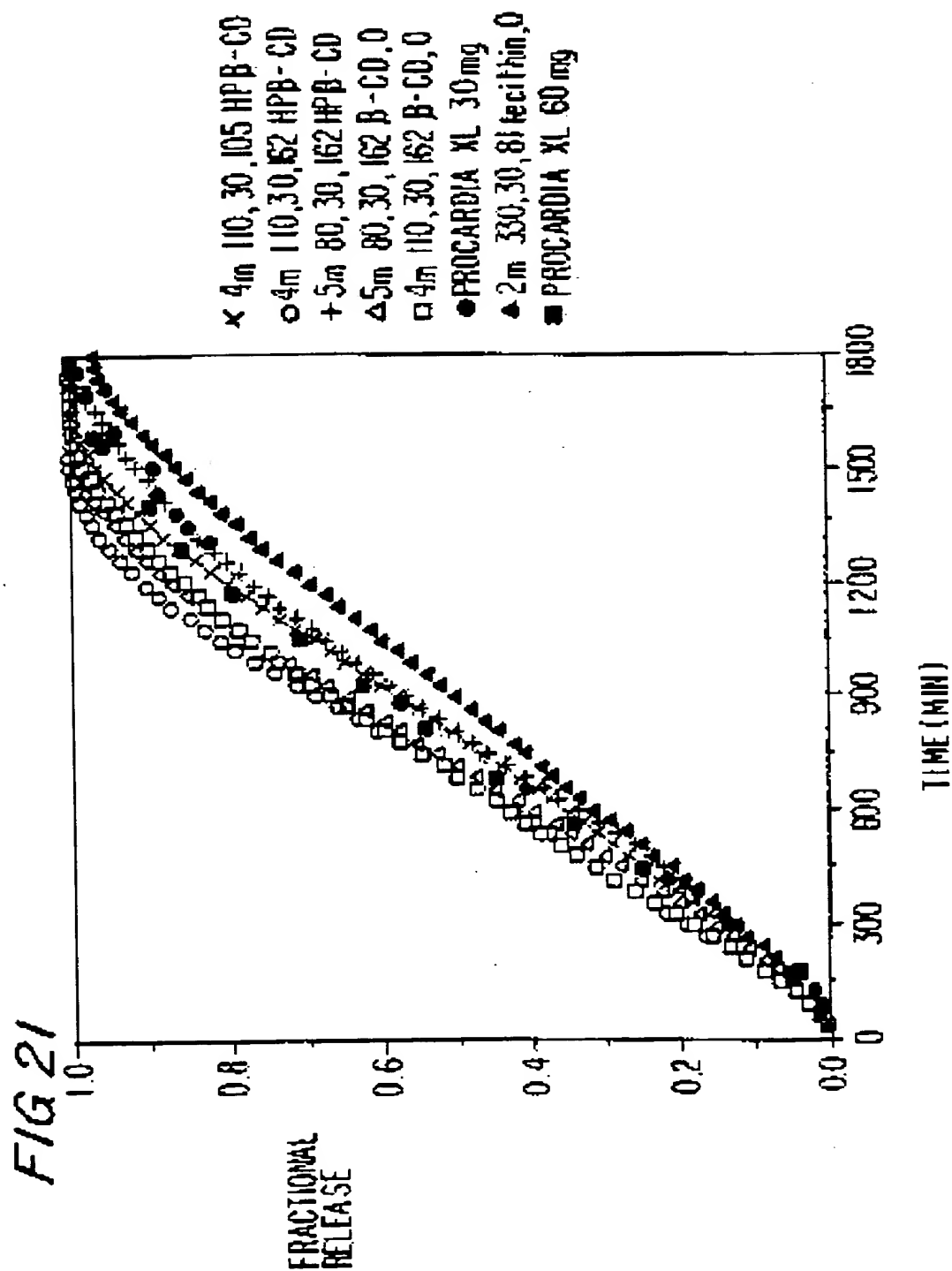


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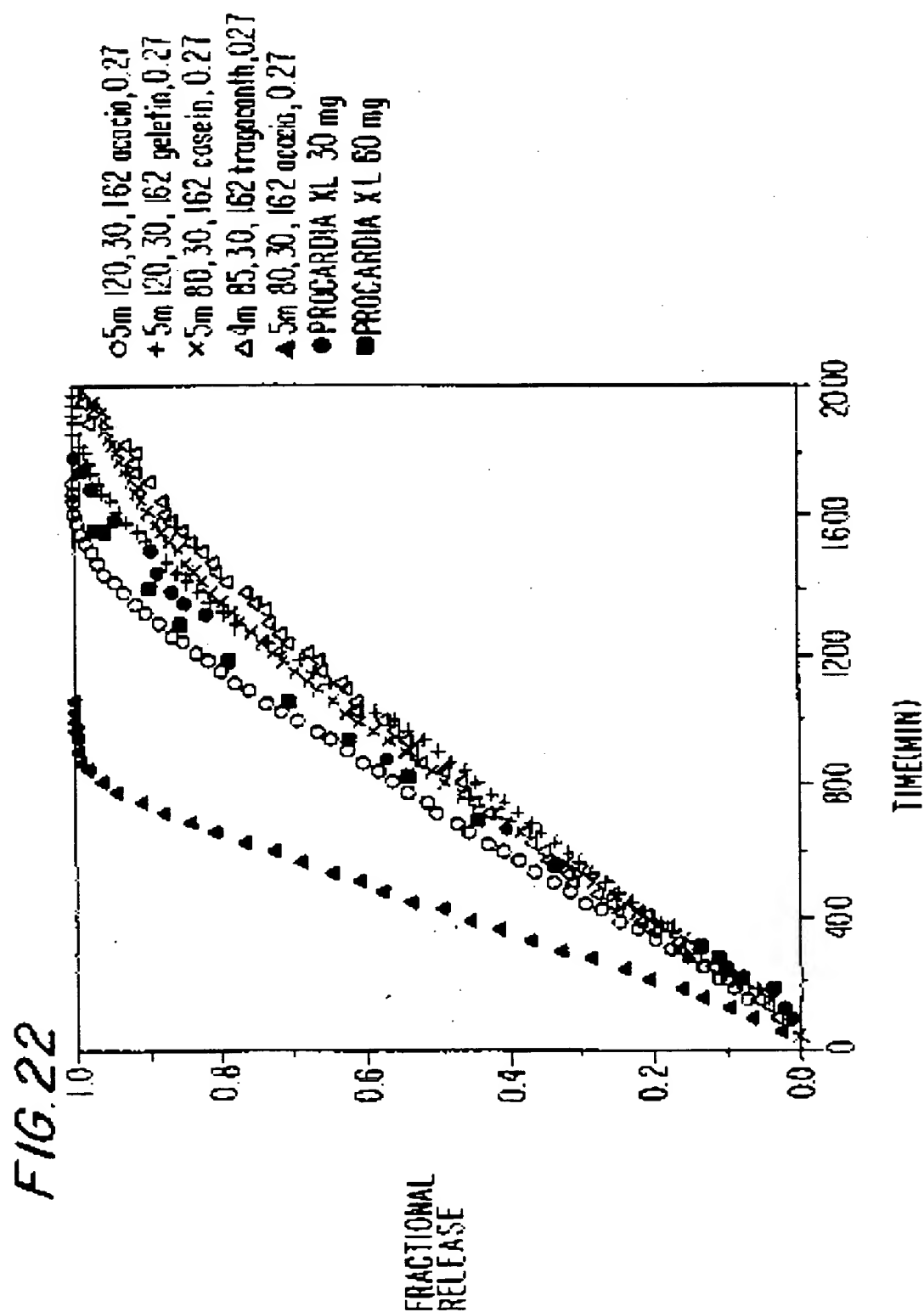
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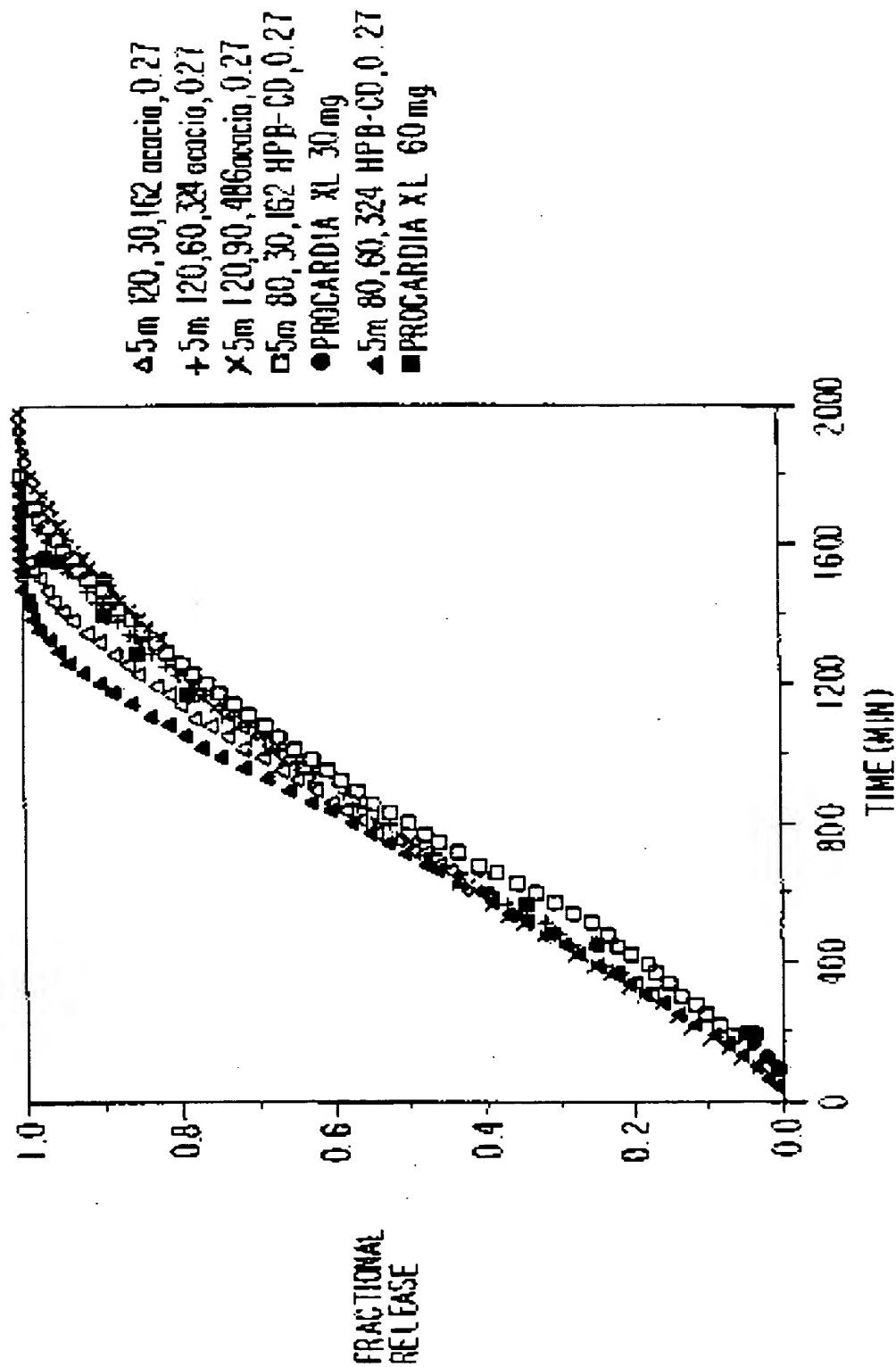


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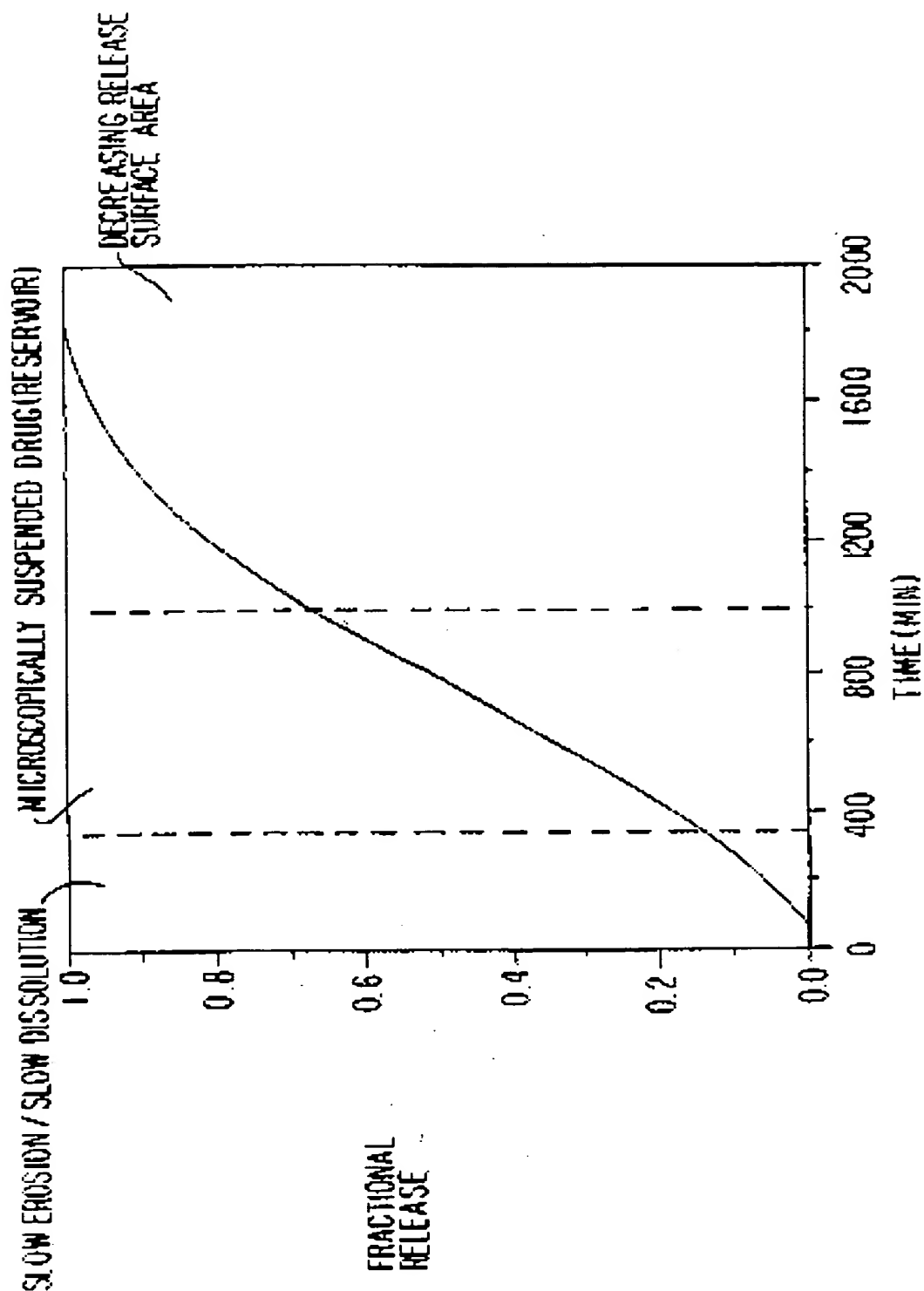
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FIG. 23

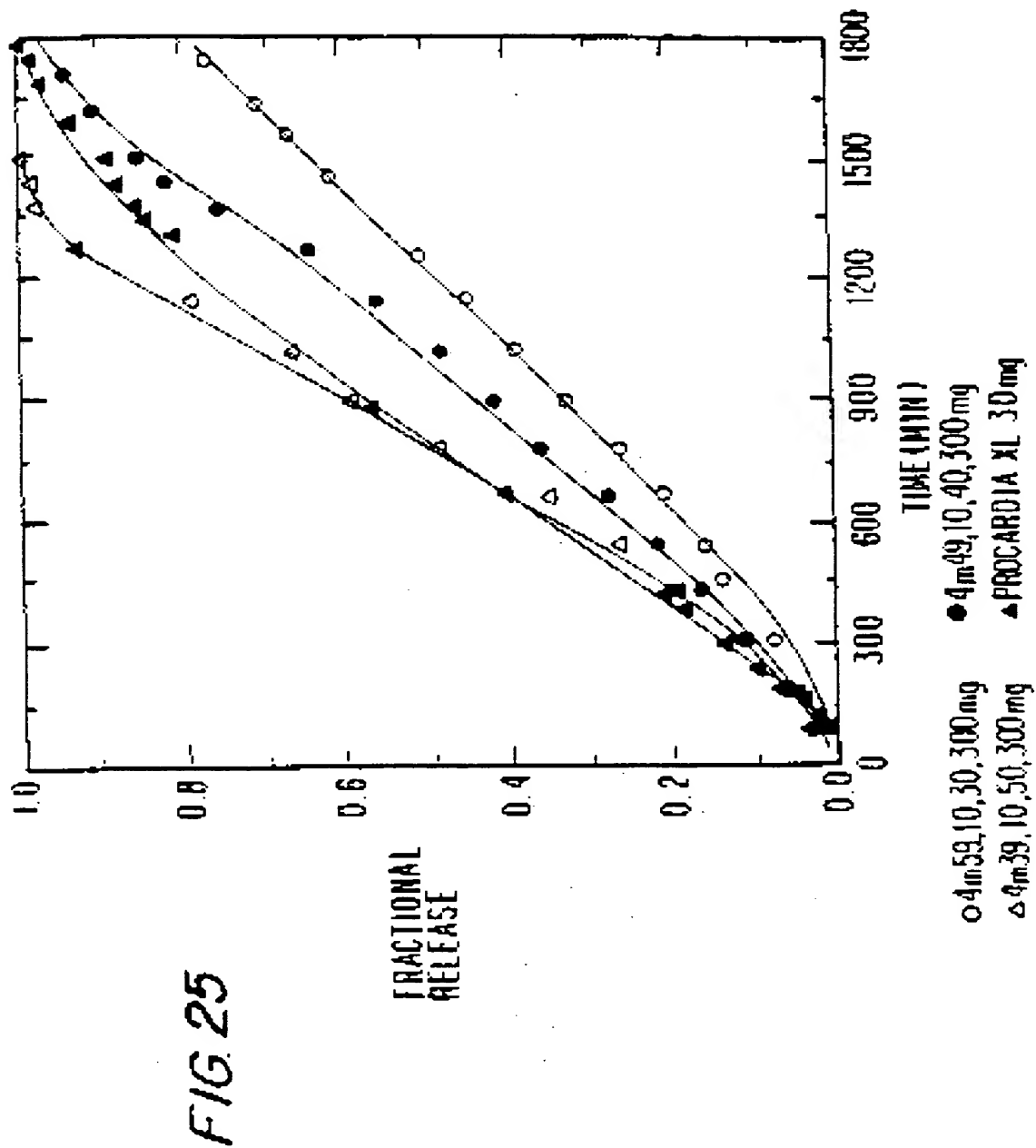


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FIG. 24

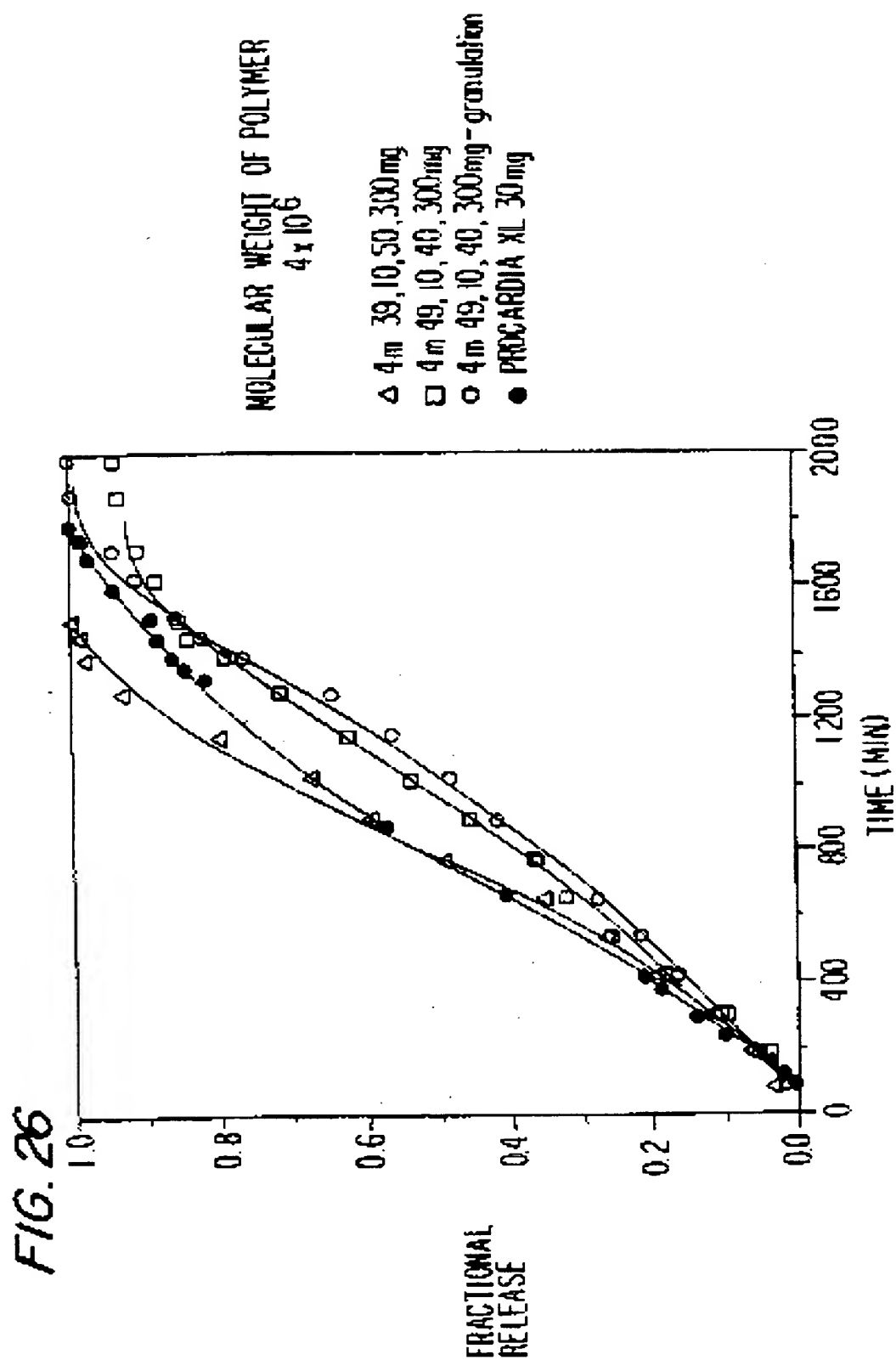


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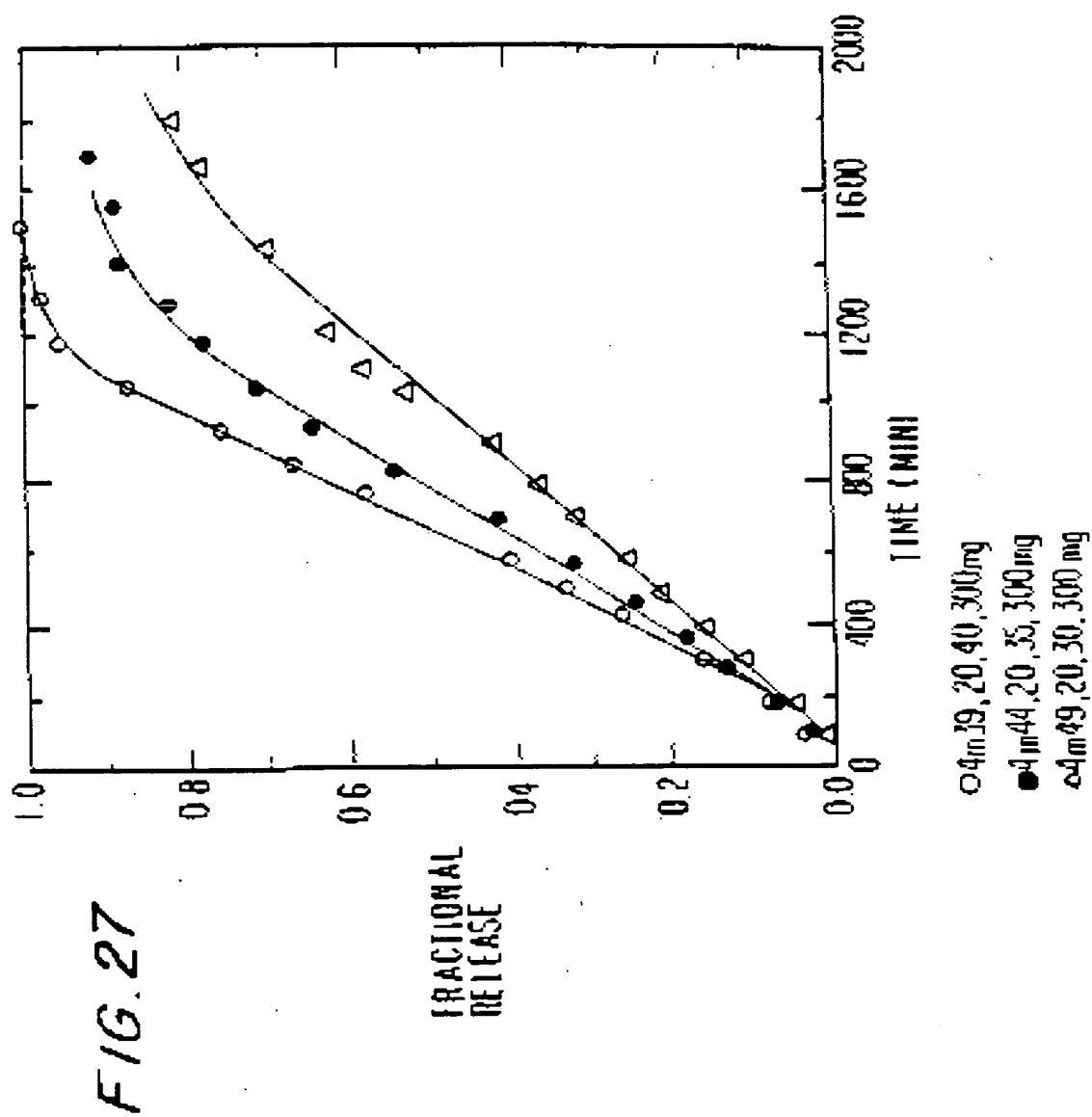


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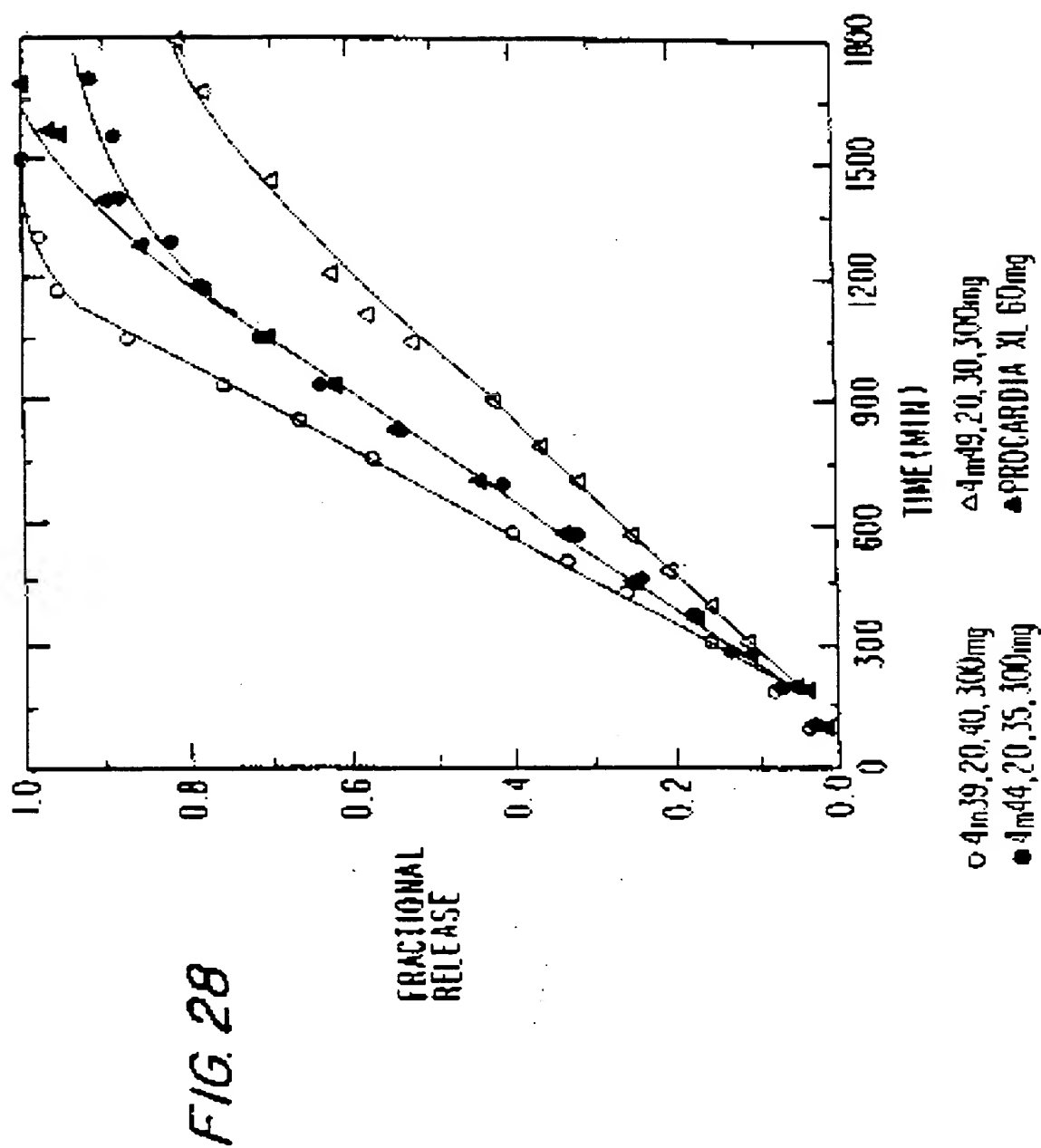


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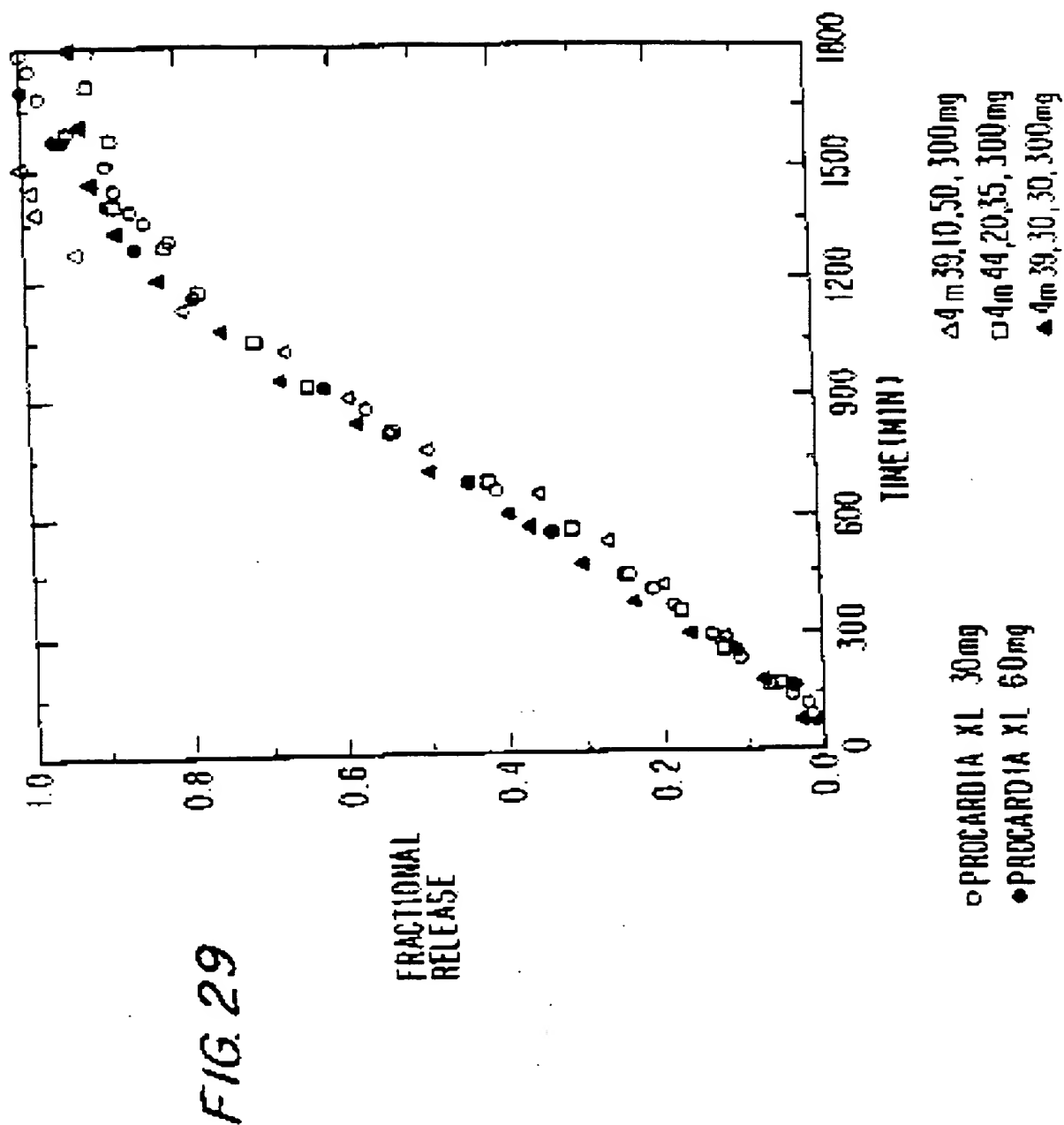


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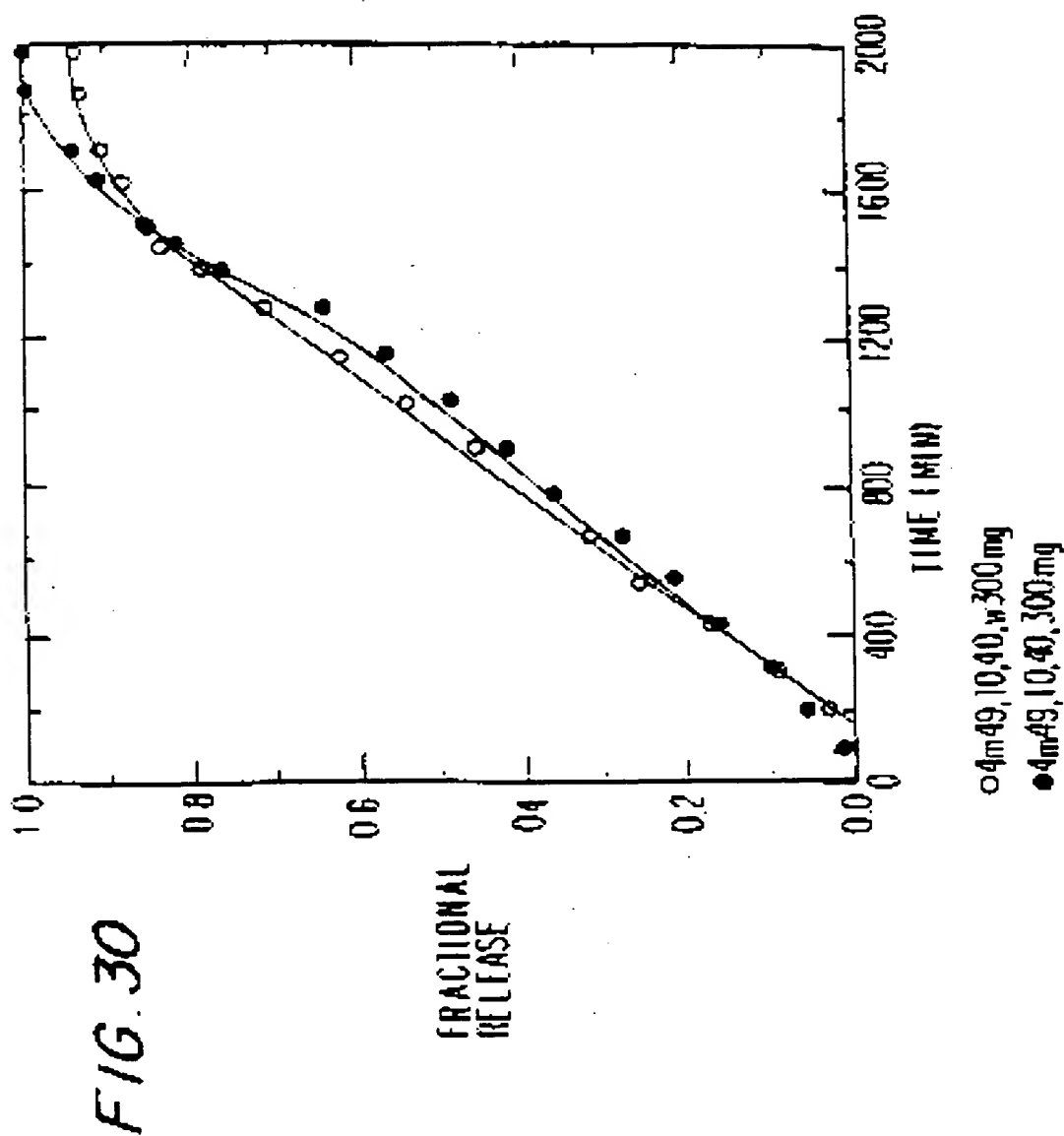


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FIG. 31

